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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
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Citizen Petition of Americans for Homeopathy Choice Foundation

Date: June 5, 2020

The undersigned, Paola Brown, President of Americans for Homeopathy Choice Foundation, submits this petition under Sections 201(g) of the Federal Food, Drug, and Cosmetic Act (FDCA or the ACT) (21U.S.C 321 (g)) and in the form required by 21 CFR Section 10.30, on behalf of herself and Americans for Homeopathy Choice Foundation, a District of Columbia nonprofit corporation recognized by the US Internal Revenue Service as a tax-exempt charitable and educational organization as described in section 501(c)(3) of the Internal Revenue Code ("AFHC") (collectively, "Petitioners).

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CITIZEN PETITION

I. **ACTION REQUESTED: That the Commissioner issue the following PROPOSED REGULATION:**

A. TITLE: HOMEOPATHIC DRUGS AND DRUG PRODUCTS LABELED "HOMEOPATHIC"

1. Definitions.

1.1. **A Homeopathic drug is any drug that contains a single active ingredient that:**

1.1.1. **is included in or certified as pending approval for inclusion in the Homoeopathic Pharmacopoeia of the United States, including its supplements and addenda (HPUS)[1];**

1.1.2. **is generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of**

[1] 21 U.S.C. § 301; 21 U.S.C. § 321(g)(1).

homeopathic drugs, as homeopathic and safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or

1.1.3. **at any time prior to June 25, 1938, was subject to the Food and Drugs Act of June 30, 1906, as amended, if its labeling contains the same representations concerning the conditions of its use as at such time;**

and contains no other active ingredients.

1.2. **A <u>Homeopathic drug product</u> is any drug product made up of two or more Homeopathic drugs, and no other active ingredients.**

1.3. **A <u>Product Labeled as Homeopathic</u> means a product that contains on its label or in its labeling any form of the term "homeopathic" that claims or implies that the product is or contains a Homeopathic drug.**

1.4. **A <u>Product Properly Labeled as Homeopathic</u> means a product that is labeled as "homeopathic" and meets the definition of a Homeopathic drug or Homeopathic drug product;**

1.5. **A <u>Product Improperly Labeled as Homeopathic</u> means a product that is labeled as "homeopathic" but does not meet the definition of a Homeopathic drug or Homeopathic drug product.**

1.6. **A product that meets the definition of a Homeopathic drug or Homeopathic drug product is not a prescription drug[2], an over-the-counter drug[3], a biological product[4], or a new drug[5].**

2. A Homeopathic Drug Shall be Deemed to be Adulterated—

2.1. **If its strength, quality, or purity differ from its description in the Homoeopathic Pharmacopoeia of the United States (HPUS).**

2.1.1. **If it purports to be or contain a drug included in the HPUS, and its strength differs from, or its quality or purity falls below, the standards set forth in the HPUS.**

2.1.2. **Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the HPUS, except that whenever tests or methods of assay have not been prescribed in HPUS, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact**

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[2] 21 U.S.C. § 353(b)(1).
[3] 21 U.S.C. § 330.1.
[4] 42 U.S.C. § 262(i)(1).
[5] 21 U.S.C. § 321(p).

to the attention of the appropriate body charged with the revision of HPUS.

2.1.3. **If such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made.**

2.1.4. **No drug included in HPUS shall be deemed to be adulterated under this section because it differs from the standard of strength, quality, or purity described in HPUS if its difference in strength, quality, or purity from such standard is plainly stated on its label.**

2.1.5. **Whenever a drug is included in the Homoeopathic Pharmacopoeia of the United States and the United States Pharmacopoeia, it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.**

2.2. **If it contains improper ingredients.**

2.2.1. **If it consists in whole or in significant part of any filthy, putrid, or decomposed substance;**

2.2.2. **If it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or**

2.2.3. **If the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of Chapter 9, Federal Food Drug and Cosmetic Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.**

3. A Drug or Drug Product Labeled "Homeopathic" Shall be Deemed to be Misbranded—

3.1. **if it displays a label or labeling that is false or misleading in any particular;**

3.2. **if it does not meet the definition of a Homeopathic drug or Homeopathic drug product;**

3.3. **if it fails to use the appropriate one of the following terms on all labels and in all labeling:**

3.3.1. **<u>"HPUS Certified:"</u> A product included in the Homoeopathic Pharmacopoeia shall carry the label "HPUS Certified."**

3.3.2. **<u>"HPUS Certified (Pending):"</u> A drug that has applied for and has been certified as accepted for review for inclusion in the HPUS, but has not yet been included shall carry the label "HPUS Certified (Pending)." Any drug or drug product applying and accepted for consideration for listing in the HPUS within the two years following the effective date of this regulation shall be considered to be an "HPUS Certified (Pending)" drug, and any such product shall be considered to be "HPUS Certified" if, within an additional four years, it is accepted for listing in the HPUS by a process certified by a recognized certifying organization.**

3.4. **If it contains on its labels or in its labeling conditions of use that differ from those described for it in the HPUS or if "HPUS Certified (Pending)," that differ from standard accepted conditions of use.**

3.5. **If it does not display the following information:**

3.5.1. **<u>Established Name</u>: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. [covered by 3.5.6]**

3.5.2. **<u>Name and Place of Business</u>: Each product must bear the name and place of business of the manufacturer, packer, or distributor in conformance with Section 502(b) of the Act and 21 CFR 201.1.**

3.5.3. **<u>Directions for Use</u>: Each drug product offered for retail sale must bear adequate directions for use in conformance with Section 502(f) of the Act and 21 CFR 201.5.**

3.5.4. **<u>Statement of Ingredients</u>: Ingredient information shall comply with Section 502(e) of the Act and 21 CFR 201.10. Labeling must bear a statement of the quantity and amount of ingredient(s) in the product in conformance with Section 502(b) of the Act, as well as 21 CFR 201.10, expressed in homeopathic terms, e.g., lx, 2x.**

3.5.5. **<u>Container Size-Labeling Exemption</u>: For those products packaged in containers too small to accommodate a label bearing the required information, the labeling requirements provided under Section 502 of the Act and 21 CFR 201 may be met by placing information on the carton or outer container, or in a leaflet with the package. However, as a minimum, each product must also bear a label containing a statement of identity and potency, and the name and place of business of the manufacturer, packer, or distributor.**

3.5.6. **<u>Language:</u> The label and labeling must be in the English language as described and provided for under 21 CFR 201.15(c)(1), although it is permissible for Industry to also include a foreign language in the labeling.**

3.5.7. **Reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.**

3.6. **If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.**

3.7. **Home Remedy Kits. Homeopathic home remedy kits may contain a number of Homeopathic drugs or Homeopathic drug products used for a variety of conditions amenable to individual use but may not contain any non-Homeopathic drugs or non-Homeopathic drug products. When limited space does not allow for those conditions to be listed on the labels of the products, the required labeling must appear in a pamphlet or similar informational piece, which is enclosed with the kits. However, at a minimum, each product must also bear a label containing a statement of identity and potency.**

4. Standards

4.1. **A Homeopathic drug shall comply with applicable Current Good Manufacturing Practice regulations and the requirements of HPUS.**

4.2. **Homeopathic drugs, when properly manufactured and labeled and evaluated under an appropriate risk-based policy, are recognized as inherently safe.**

4.3. **An appropriate risk-based policy requires that the risk of Homeopathic drugs and Homeopathic drug products be evaluated in relation to the risks presented by other regulated products.**

4.4. **Absent a determination that any specific Homeopathic drug or any specific Homeopathic drug product is a new drug, FDA will treat all Homeopathic drugs and Homeopathic drug products as generally recognized as safe and effective for their intended use (GRAS/E), subject to compliance with provisions of this regulation addressing adulteration and misbranding, and Current Good Manufacturing Practice regulations.**

II. STATEMENT OF GROUNDS

A. Introduction

In order to ensure full access to properly labeled and manufactured homeopathic drugs for the consumers who choose to use them, and to protect consumers from drug products improperly labeled “homeopathic,” Petitioners ask the FDA to adopt the above-proposed regulation on the following grounds:

- FDA has made, and needs to clarify, conflicting statements in the public record concerning the nature of and the manner in which it intends to regulate homeopathic drugs;[6]

- FDA has proposed changes in the manner it intends to regulate homeopathic drugs, shifting from the standards it applied between 1938 and 2017 to those announced in its 2017/2019 proposed guidance in ways that petitioners assert are not in accordance with the law; and

- FDA's proposed guidance states, "You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations." Petitioners offer the alternative approach set forth in the regulation proposed herein and assert that the proposed regulation not only "satisfies the requirements of the applicable statutes and regulations" but also that the law requires FDA to regulate homeopathic drugs as a distinct class of products under the Food Drug and Cosmetic Act in the manner set out by petitioners in their proposed regulation.

B. Executive Summary

Petitioners seek to have FDA establish regulations that would assure consumers: that drug products labeled "homeopathic" are either included in the HPUS or can be reasonably expected to be accepted for inclusion in the HPUS because they meet eligibility thresholds, as determined by relevant third-party review; that products that do not meet the foregoing criteria are not permitted to be labeled "homeopathic;" that homeopathic drugs are free of adulteration and properly labeled; and that FDA applies standards appropriate for low-risk products when evaluating the risks of homeopathic drugs. Further, petitioners seek recognition by FDA that homeopathic drugs, properly manufactured and labeled, and evaluated by appropriate standards, do not meet the legal definition of "new drugs," and therefore are not subject to premarket review other than satisfying the requirements of current or likely inclusion in the HPUS.[7]

Currently, only homeopathic drugs and drug products that appear in the Homeopathic Pharmacopoeia of the United States (HPUS)[8] or its supplements or addendums are recognized by the FDA as properly labeled. Many products labeled homeopathic but not in the HPUS would qualify to be listed in the HPUS. There is a process for adding new products to the HPUS and its supplements. This petition seeks a two-year grace period[9] for products to be proposed and accepted for review for addition to the HPUS and an

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[6] For example, in its 2019 Proposed Guidance, Drug Products Labeled as Homeopathic, the words "homeopathic drug product(s)" appear in lines 16, 21, 25, 54, 62, 69, 78, 79, 81, 88, 95, 97, 98, 102, 107, 117, 122, 124, 138, 145,147,152, 155. A search for the words "Drug Product labeled as Homeopathic" found them only in the title and not in the body of the guidance. This dichotomy creates serious confusion for consumers, producers and practitioners.

[7] The FD&C Act and PHS Act do not include a requirement for premarket review of homeopathic drugs. Unless otherwise specifically determined by FDA, in accordance with defined administrative procedure, no homeopathic drug is a "new drug" under section 201(p) of the FD&C Act).

[8] The HPUS is declared a legal source of information on homeopathic drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301. Section 201(g)(1) of the Act. 21 U.S.C. § 321 defines the term "drug" as articles recognized in the official United States Pharmacopoeia, official Homœopathic Pharmacopœia of the United States, or official National Formulary or any supplement to any of them.

[9] Appendix #1: "Operation Plan for Adding Drugs to HPUS."

additional four years for the applications to be accepted or rejected by a process certified by a recognized certifying organization such as the International Standards Organization (ISO) or the American National Standards Institute (ANSI). There are also a variety of drug products on the market that are labeled "homeopathic" but are neither included in the HPUS nor would they qualify for inclusion, and which have the potential to mislead and in some cases harm consumers. This petition seeks a clear FDA enforcement position that any drug product improperly labeled "homeopathic" is deemed to be misbranded.

This petition seeks the appropriate application of a sound risk-based policy for homeopathic drugs and homeopathic drugs products that recognizes homeopathic drugs as low-risk compared to other products regulated by the FDA. Between 1938 and 2017, under the legal authority granted to it and, petitioner believes, required by the Food, Drug, and Cosmetic Act of 1938, FDA recognized homeopathic drugs as part of a unique form of medicine which when properly manufactured and labeled, under Current Good Manufacturing Practices and the HPUS, were inherently safe.

This petition seeks implementation of a process in which risk-based policy can be used to regulate drug products improperly labeled "homeopathic" without endangering properly manufactured and properly labeled traditional homeopathic drugs.

C. Purpose of the Petition

The purpose of this Citizen Petition is:

1. To establish a final rule setting out regulations for the manufacture and sale in the United States of homeopathic drugs and homeopathic drug products and ensuring that only products meeting the definition of homeopathic drugs and drug products are labeled as homeopathic.

2. To complete the process begun by FDA with the March 27, 2015, announcement entitled, "**Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing: A Proposed Rule by the Food and Drug Administration**."[10] The 2015 FDA announced process was to hold a public hearing and establish a final rule for Homeopathic Product Regulation. The Agency has yet to establish a final rule and in April 2015, held an informal public meeting rather than following the Administrative Procedures Act and holding a formal public hearing identified in its announcement.

3. To establish that if the FDA adopts a risk-based policy for drug products labeled as homeopathic, that policy is properly developed and applied to homeopathic drugs and drugs products labeled as homeopathic, to ensure that the risk presented by homeopathic drugs and drug products would be properly evaluated which, based on past history and current science, world place homeopathic

[10]Appendix #2: 80 Fed. Reg. 16327, "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing." https://www.govinfo.gov/content/pkg/FR-2015-03-27/pdf/2015-07018.pdf

drugs and drug products in the lowest category of risk for products regulated by the FDA.[11]

4. To request that, if the Agency fails to grant this petition, it hold a public hearing on this petition in accordance with the requirements of the Administrative Procedures Act.

D. Background of Petition

1. Petitioners

1.1. ***Americans for Homeopathy Choice Foundation*** exists to ensure consumer access to homeopathic drugs that meet the standards for strength, quality, and purity set forth in the Homoeopathic Pharmacopoeia of the United States, and its supplements (HPUS), Section 501(b) of the FDCA (21 USC 351 (b)). Our members and leaders use homeopathy for their health and the health of their families. Petitioner Paola Brown is the President of Americans for Homeopathy Choice Foundation and a consumer of homeopathic drugs and homeopathic drug products.

1.1.1. As a non-partisan community organization, we support the rights of the 7 million, and growing, Americans and their families who use homeopathic drugs, homeopaths and other health professionals who use homeopathic drugs to support their clients, and homeopathic pharmacies and other producers that manufacture and distribute homeopathic drugs in the United States.

1.1.2. Our organization is run by volunteers—mostly made up of mothers -- and we are funded by donations from people who believe in our mission. Our internet presence is strong and growing with 56,390 unique visitors (since January 1, 2020) on our website and ~25,000 visitors weekly on social media, with 100 new followers added each week. These numbers reflect a significant grassroots movement run by mothers, parents, and others who care deeply about their freedom to access homeopathic drugs and homeopathic drug products.

2. Properly Labeled Homeopathic Drugs vs. Drug Products Improperly Labeled as "Homeopathic"

2.1. **Homeopathic Drugs:** All drugs that appear in or are pending approval[12] for inclusion in the Homeopathic Pharmacopoeia of the United States[13] (HPUS) or its supplements are homeopathic drugs if prepared according to the guidelines recorded in HPUS, an addendum to it, or its supplements[14] by serial dilution and succussion, and consisting of only one active ingredient.

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[11]Appendix #3: "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic." Also see section F. of this petition.

[12]*p. cit.,* fn 9: Appendix #1, "Operation Plan for Adding Drugs to HPUS."

[13] *Op.cit*., fn 8. [*"Op. cit.*" should start with a capital letter when it begins a footnote and be in italics.]

[14] Appendix #4: "Supplements to the Homoeopathic Pharmacopeia of the United States."

While the exact number of homeopathic products is unknown, petitioners estimate that there are 6000 products on the market that are labeled as "homeopathic." Approximately 1250 are homeopathic by virtue of the fact that they are listed in the HPUS. At least half of the remainder are eligible for review for inclusion in the HPUS but have not yet been reviewed for inclusion. The remainder are improperly labeled "homeopathic."

2.2. **Homeopathic Drug Products**: Homeopathic Drug Products are drug products made up of two or more homeopathic drugs and no other active ingredients.

2.3. **Drug Products Improperly Labeled as "Homeopathic**:" Some drug products labeled as homeopathic are, in fact, not homeopathic because they cannot meet the qualifications for inclusion in the HPUS and/or they are either mislabeled or improperly manufactured. In this case, mislabeled means the drug product labeled as homeopathic is not listed in HPUS, an addendum to it, or its supplements, and is not pending approval for inclusion in the HPUS. Petitioners seek policies that will address products improperly labeled as "homeopathic" without limiting consumer access to properly labeled and manufactured traditional homeopathic drug products.

2.4. **Consumers Want Access to Homeopathic Drugs:** A continually increasing number of consumers have chosen to use homeopathic drugs since 1988 when CPG 400.400 was adopted by the Agency as the guidance for enforcement of FDA policy and regulations with regard to marketing homeopathic drug products. This continued expansion of use underscores the fact that consumers see value in homeopathic drugs. Consumers need and want regulations that protect them from mislabeled or improperly manufactured drug products labeled as "homeopathic" while ensuring their continued access to properly labeled and manufactured traditional homeopathic drugs.

3. **Homeopathic Drugs Pose a Minor Risk**

3.1. **Risk-Based Policy**. Applying FDA's interest in its general risk-based approach to enforcement to properly labeled and manufactured homeopathic drugs establishes the fact that the safety record of homeopathic drugs places them in the lowest possible risk category. Petitioners have addressed this in "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic," attached to this petition as Appendix #3.[15]

3.2. **Safety of Drug Products Labeled as "Homeopathic**:" The recent growth of safety concerns expressed by the FDA concerning drug products labeled as "homeopathic" (products asserted by the Agency to be associated with serious adverse events and otherwise presenting significant safety risks and egregious violations of CGMP requirements) have all been due to improper

[15] *Op. cit.,* fn 11, Appendix #3: "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic."

labeling or manufacturing. The public record reveals none that have been traced to properly labeled and manufactured homeopathic drugs.

3.2.1. FDA claimed in its 2017/2019 proposed guidance that since the issuance of CPG 400.400 in 1988, FDA had encountered multiple situations in which a product labeled as "homeopathic" posed a significant risk to consumers. Such products, FDA said, either caused or could have caused significant harm, even though the product labeling and ingredient formulation appeared to meet the conditions of CPG 400.400, when in fact the formulations and labeling did not. Petitioners have found evidence that all instances of harm cited by the FDA occurred in products labeled as "homeopathic," but which did not qualify as homeopathic by virtue of not being listed in the HPUS or not being properly manufactured or offered for use in accordance with HPUS standards.

3.2.2. For example, in 2016, FDA's search of the FDA Adverse Event Reporting System (FAERS)[16] database identified 99 cases of adverse events consistent with symptoms of belladonna toxicity, including reports of infant deaths and seizures possibly related to teething products.

- After careful review, FDA was unable to determine if any of these products caused harm. FDA did determine that there were products labeled as "homeopathic" that were improperly labeled and/or manufactured but did not determine that these products caused harm. Multiple drug products labeled as "homeopathic" were identified as associated with this safety concern.

- Further investigation revealed that the belladonna alkaloids in some of the products exceeded the labeled amounts.

3.2.3. As another example, by 2009, FDA had received more than 130 reports of anosmia (loss of the sense of smell) associated with the use of Zicam intranasal zinc products (products improperly labeled as "homeopathic"). FDA determined that if the products were used as directed in the labeling, a user would receive significant daily exposure to intranasal zinc, raising a serious safety concern.

- The Zicam on which these reports were received was misrepresented as a homeopathic drug product and should not have been labeled "homeopathic."

- While labeled "homeopathic," neither Zicam nor the teething products referenced above met the stringent criteria listed in HPUS that allow them to be labeled as homeopathic, because they were either improperly manufactured or contained improper directions for use.

3.2.4. FDA states that Teething Tablets and Zicam are only two examples among many. Petitioners have asked FDA for but been unable to obtain

[16] Appendix #5: "Limitations of FAERS Database".

the names of any other drug products labeled as “homeopathic” that the FDA believes to have caused harm.

3.2.5. FDA has also alleged many serious violations of Current Good Manufacturing Practice requirements by manufacturers of products labeled as “homeopathic.” An improperly manufactured homeopathic drug is a defective product just as any other product regulated by the FDA would be, and its lack of safety has no bearing on the safety of a properly manufactured and labeled homeopathic drug.

3.3. All of the evidence Petitioners have seen from FDA supports the fact that no homeopathic drug or homeopathic drug product that was properly labeled and complied with Current Good Manufacturing Practice regulations caused any harm.

3.4. All alleged harm attributed to drug products labeled as “homeopathic” has been traced to products that have failed to meet either FDA labeling regulations or CGMPs.

3.5. “See section F.3, Legal Authority-Risk-Based Policy,” for a more detailed discussion of risk-based policy for homeopathic drugs and drug products labeled as “homeopathic.”

E. Background on Homeopathy

1. History of Homeopathy

1.1. Homeopathy is the medical art and the science that utilizes medicines capable of producing symptoms in healthy individuals to resolve illness in those who are unwell. Any substance may be considered a homeopathic drug if it has a known "homeopathic proving," or meets other certified standards.

1.2. Homeopathic drugs are intended to diagnose, cure, mitigate, treat or prevent specific diseases as a result or by-product of the application of the homeopathic drug to the specific set of symptoms discovered or described in a specific patient. When applied by the governing principles of science, they are meant to assist the body’s self-healing mechanisms so that homeostasis is regained. Two hundred years of use and current scientific knowledge indicate that homeopathic drugs, when potentized[17] (diluted and succussed), work by non-chemical means consistent with the non-pharmacological properties observed in nanoparticles.[18,19,20] To be most effective, homeopathic care is individualized.

1.3. Central to homeopathy is the determination of the effect of substances on healthy volunteers through “provings” and the use of the developed "drug pictures" produced by those provings by the consumer and/or trained health

[17] The process of potentization requires serial steps of dilution accompanied by vigorous succussion at each step. This process can be accomplished by hand or machine.

[18] Bell IR, Koithan M. A model for homeopathic remedy effects: low dose nanoparticles, allostatic cross-adaptation, and time-dependent sensitization in a complex adaptive system. *BMC Complementary and Alternative Medicine* 2012;12:191.

care provider according to the homeopathic Principle of Similars ("*similia similibus curentur*" – "Let likes be cured by likes")[19].

1.4. Historically, homeopathy has been practiced by medical doctors, allied medical personnel, paramedical practitioners, and by the general public for self-care. Homeopathy is an ideal therapeutic medium for self-medication of symptoms associated with self-limiting conditions since the selection of the proper drug for each case is dependent on the symptoms that the body exhibits in its reaction to the illness. For the use of homeopathy in conditions that are other than self-limiting, the consumer is advised to employ the services of a licensed or certified health care provider.

1.5. Homeopathy is a widely used medical practice that has a theoretical basis dating at least back to the Greek physician Hippocrates (460–370 BC), known as the "father of medicine" who stated, "first do no harm" (*primum non nocere*) and reasoned that illnesses could be treated either with similars or opposites. During the Renaissance, the Swiss physician Theophrastus von Hohenheim, known as Paracelsus (1493-1541), pioneered a medical revolution by emphasizing the value of observation along with a consideration of the toxicology of substances used as medicines. He stated that "The art of healing comes from nature, not from the physician. Therefore, the physician must start from nature, with an open mind."[20]

1.6. Homeopathy was formally delineated as a system of medicine in the late 18th century by the German physician and scholar Samuel Christian Hahnemann (1745-1843). Hahnemann's early success with homeopathic treatment in the epidemics of Typhus, Scarlet Fever, and Cholera led to its acceptance and dissemination throughout the world. It was eventually introduced into the US in New York City by Boston-born physician Hans Burch Gram in 1825. Gram trained his colleagues to use homeopathy, and by the time of the city's Cholera epidemic of 1832, it was evident that homeopathy had established a well-deserved place in public health care, particularly in the treatment of epidemic diseases.[21]

1.7. In 1844, the American Institute of Homeopathy (AIH) was founded in New York City.[22] By 1900 there were more than 14,000 homeopathically trained physicians, 22 homeopathic medical schools, and well over 100 homeopathic hospitals and mental institutions[23] across the US. After the 1910 Flexner

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[19] See section 2 (Principles) for definition of Law of Similars.

[20] Ramseyer AA, transl. Paracelsus and his Medical Doctrines, Chapter II in Rademacher's Universal and Organ Remedies (Erfahrungsheillehre). Boericke & Tafel, Philadelphia, PA 1909:3-7.

[21] Appendix #6: "Epidemic Infectious Diseases, Public Health and Homeopathy," Andre Saine, ND.

[22] The AIH remains America's oldest, extant, national medical association, predating the foundation of the American Medical Association (AMA) by three years.

[23] American Institute of Homeopathy. Report on Homeopathic Organizations in the United States: "Homeopathic hospitals, sanitoriums and dispensaries in the USA in 1908;" In 1908 there were a total of 192 hospitals and sanatoriums [sic] using homeopathy (99 exclusively homeopathic public and private hospitals, 40 mixed homeopathic and allopathic, 49 sanitoriums using exclusively homeopathy, and 4 sanitoriums using mixed homeopathic and allopathic).

Report[24] initiated the closure or conversion of homeopathic medical schools, the practice of this medical specialty diminished significantly.

1.8. In 1918 Royal S. Copeland, MD (1868 –1938), a homeopathic physician, ophthalmologist, former President of the American Institute of Homeopathy and Dean of New York Homeopathic Medical College/Flower Fifth Avenue Hospital[25] was appointed President of the New York City Board of Health, where he achieved superlative results in that city's 1918 epidemic of Spanish Flu.[26] From 1924–1938, Copeland served as the United States Senator from New York, where he sponsored the Food, Drug, and Cosmetic Act of 1938. That Act, which was passed by Congress and signed by the President in 1938, formally recognized the Homeopathic Pharmacopoeia of the United States and defined homeopathic medicines as drugs.

1.9. Today, more than 500 million people throughout the world use homeopathy[27] , and more than 250 thousand physicians prescribe it.[28] Homeopathic medicine is the second most common form of alternative medicine in the world today.[29] It is practiced in nearly every country and continent in the world. In the US, it is currently utilized by about 3% of the population.[30]

1.10. There is a robust database of peer-reviewed scientific research in both clinical and preclinical investigations, including cohort studies, randomized-placebo-controlled trials, comparative effectiveness research, and meta-analyses demonstrating benefits in a wide range of medical conditions, with an unparalleled safety profile and patient satisfaction rates.[31] It is the fastest-growing form of non-pharmaceutical medicine in the United States. Homeopathy is an important consumer choice, an essential component of public health, and boasts a firm evidence-base.[32]

2. **Principles of Homeopathy**

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[24]Flexner, Abraham (1910), Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching (PDF), Bulletin No. 4., New York City: The Carnegie Foundation for the Advancement of Teaching, p. 346, OCLC 9795002, retrieved June 8, 2015.*The Flexner Report* (Carnegie Foundation Bulletin Number Four) is a book-length landmark report of medical education in the United States and Canada, written by Abraham Flexner and published in 1910 under the aegis of the Carnegie Foundation: Flexner, Abraham (1910), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2567554/ Winston, J., "The Faces of Homeopathy. An illustrated history of the first 200 years." Great Auk Publishing. 1999

[25]Now New York Medical College.

[26] Aimone F. The 1918 Influenza Epidemic in New York City: A Review of the Public Health Response. Public Health Rep 2010; 125(Suppl 3): 71–79.

[27] Bell IR, Schwartz GE. Adaptive network nanomedicine: an integrated model for homeopathic medicine. Frontiers in Bioscience (Scholar Ed.). 2013;5(2):685-708

[28] https://www.ncbi.nlm.nih.gov/pubmed/20471616

[29] WHO Global Atlas of Traditional Complementary and Alternative Medicine (Map Volume); C.K. Ong, G. Bodeker, C. Grundy, G. Burford and K. Shein; Kobe Japan; 2005.

[30] Dossett ML, Davis RB, Kaptchuk TJ, et al. Homeopathy Use by US Adults: Results of a National Survey. *Am J Pub Health* 2016; 106(4): 743–745.

[31] https://homeopathyusa.org/uploads/Homeopathy-Research-Evidence-Base-12-13-2019.pdf and https://www.hri-research.org/hri-research/accessed online 06 April 2020.

[32] https://homeopathychoice.org/research/

2.1. There are four main clinical principles upon which homeopathy is empirically based:[33]

- The Law of Similars, which is fundamental to homeopathic practice, describes the observed phenomenon that medicines, selected on the basis of their capacity (previously demonstrated in a "proving"[34] or by other methods) to produce symptoms in healthy subjects, can be used to cure, treat, mitigate and prevent various diseases in those suffering from a similar malady.

- Holism and psychosomatics describe the mind-body phenomena that coexist in health and illness.

- Homeotherapeutics describes the reproducible and predictable patterns by which illness develops, and health is restored. It relies on careful history-taking to select the most appropriate drug that matches identifiable symptoms produced by drugs, through "provings" or other methods, with symptoms expressed by the individual patient.

- Minimum dose describes the phenomenon that when a homeopathic drug is selected on the basis of these three principles, then only minute amounts of that drug are needed to cure, treat, mitigate, and prevent various diseases.

3. **The Homoeopathic Pharmacopoeia of the United States (HPUS)[35]**

3.1. The Homoeopathic Pharmacopoeia of the United States (HPUS) has been in continuous publication, expansion, and revision since it was formed by the Committee on Pharmacy of the American Institute of Homeopathy (AIH) in 1897. The Food Drug and Cosmetic Act of 1938 included the HPUS and its supplements in its definition of drugs. In 1980 the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) was established to continue maintaining and supplementing the HPUS[36] as an independent and authoritative source of drug information.[37] Drugs in the HPUS have been, and continue to be, subject to FDA drug labeling and current Good Manufacturing Practices (CGMP) regulations.

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[33] Boericke G. A Compend of the Principles of Homoeopathy for Students in Medicine. World Homeopathic Links, New Delhi, India, 1980.

[34] A homeopathic drug proving represents one of the fundamental principles in homeopathy. Together with empirical clinical observations and toxicological data, it forms the basis of the drug picture of a homeopathic drug. Samuel Hahnemann, the founder of homeopathy, was the first to systematically carry out homeopathic drug provings. Drug provings, in a general sense, existed before this time. Predecessors of Hahnemann, Anton Stoerck, William Alexander, and Albrecht von Haller began testing medicinal substances on healthy subjects in the 18th century. Hahnemann put these investigations into a therapeutic context utilizing the scientific methodology of his day.

[35] *Op. cit.*, fn 8.

[36] HPCUS has undertaken the task of maintaining and continuously supplementing the HPUS. The HPUS consists of the 1938 HPUS supplemented by the Eighth Edition, Volume I (1979); the Compendium of Homeotherapeutics (1974); and "Supplement A" of the HPUS Eighth Edition (1982) into one HPUS compilation currently maintained by the HPUS Revision Service. In CPG 400.400, FDA said, "Homeopathic Drug: Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopoeia of the United States (HPUS), an addendum to it, or its supplements."

[37] http://www.hpus.com/what-is-the-hpus.php

3.2. In 1938, when the Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted, it defined drugs as "articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them."[38] Recent years have seen an increase in the sale of homeopathic drugs. In the past, these products were mostly prepared by homeopathic physicians for individual patients. Today, they are frequently mass manufactured and widely marketed as direct to consumer products subject to FDA drug labeling and current Good Manufacturing Practices (CGMP) regulations.[39]

3.3. The definition of "drug" in section 201(g)(1) of the FD&C Act (21 USC 321(g)) includes, among other articles, articles recognized in the HPUS or any of its supplements. As such, homeopathic drugs are subject to the same manufacturing and labeling regulatory requirements as other drugs. A homeopathic drug that has been monographed[40] in the HPUS, or that is pending approval for inclusion in HPUS, is not a new drug. [41] Any drug that is generally recognized as safe and effective (GRAS/E) by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling is not a new drug.[42]

4. FDA and the HPUS

The FDA has acknowledged the value and importance of the HPUS:

4.1. On April 1,1983 FDA stated in its rulemaking process that: "...the agency believes that the quality controls required by the other portions of the CGMP regulations and the requirements of 'The Homeopathic Pharmacopoeia of the United States' are sufficient to ensure the quality of homeopathic drug products."[43]

4.2. In the same announcement, FDA stated its belief that the assurance of the quality of homeopathic drugs can be achieved "...by adherence to the other requirements of the CGMP regulations and to the quality and production standards of The Homeopathic Pharmacopoeia of the United States."

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[38] Section 201(g)(1)(A) of the FD&C Act.

[39] Appendix #7, 48 Fed. Reg. 64, 14004 (April 1, 1983) "...the agency believes that the quality controls required by the other portions of the CGMP regulations and the requirements of "The Homeopathic Pharmacopoeia of the United States" are sufficient to ensure the quality of homeopathic drug products." https://www.govinfo.gov/content/pkg/FR-1983-04-01/pdf/FR-1983-04-01.pdf

[40] Appendix #8, "Homeopathic Monographs Added to the Homeopathic Pharmacopoeia Since 2000."

[41] FDA has not determined that any homeopathic drug is a "new drug." Petitioners assert that no aspects of the FD&C Act require prior approval before the marketing of homeopathic drugs.

[42] Section 201(p) of the FD&C Act. The term "new drug" means—

> **(1)**Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;...

[43] *Op. cit.*, fn 39, Appendix 7: 48 Fed. Reg. 64, 14004 (April 1, 1983). https://www.govinfo.gov/content/pkg/FR-1983-04-01/pdf/FR-1983-04-01.pdf

4.3. In 2004, as part of a general withdrawal of 81 unfinalized proposals, this 1983 proposed rule was withdrawn. The Agency noted (in Note 11) the importance of addressing manufacturing and labeling errors. The agency did not change its stated view that CGMP and HPUS combined are sufficient to ensure the quality of homeopathic drug products.

F. Legal Authority

Between 1938 and 2017, FDA treated homeopathy as a unique form of medicine and considered it to be inherently safe, and not subject to risk/benefit premarket approval, but subject solely to regulation for compliance with proper labeling and manufacturing rules. In 2017 FDA announced a guidance reversing 79 years of policy, saying it would apply the law as if homeopathic drugs were required to file new drug applications.

1. Legislative Background

The US Food Drug and Cosmetic Act of 1938, as amended, is a law designed to protect, advance, and empower the consumer interest in a safe and effective food and drug supply. In addition to strengthening food, drug, and cosmetic regulation in the United States, the 1938 Act repealed the Pure Food and Drug Act of 1906.

1.1. Definition of "drug"

The 1938 FDCA prohibits adulteration and misbranding of any and all food and drug products, including homeopathic products. The Act defines a "drug" (US Code § 321) saying:

> (g)(1)The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, **official Homoeopathic Pharmacopoeia of the United States**, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) (emphasis by petitioners).

1.2. Definition of "new drug"

In 1962, in large measure as a response to the Thalidomide tragedy [44] during which a pharmaceutical drug caused thousands of children to be deformed at birth, Congress passed the Kefauver-Harris Drug Control Act (the 1962 New Drug Amendments). In addition, requiring a pharmaceutical drug manufacturer to establish safety as required by the 1938 Act, the 1962 act further amended §321of the US Code requiring that all sponsors of "new drugs" establish that substantial evidence of efficacy for the claims made for the "new drug" existed before a drug could be approved for marketing. The 1962 act did this by

[44] The thalidomide disaster is one of the darkest episodes in pharmaceutical research history. The drug was intended as a mild sleeping pill safe even for pregnant women. However, it caused thousands of babies worldwide to be born with malformed limbs. The damage was revealed in 1962. http://broughttolife.sciencemuseum.org.uk/broughttolife/themes/controversies/thalidomide.

requiring a sponsor to file a new drug application (NDA) for approval by the FDA and adding a definition of a “New Drug” to the law (§321) saying:

> (p)The term “new drug” means—
>
> (1)Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;

Under this 1962 law, products that qualified as “New Drugs” were required to receive approval from FDA that they were shown to be safe and effective.

The law required proponents for marketing a new drug (almost exclusively their manufacturers) to receive approval of FDA before marketing the drug. The law says:

> No person shall introduce or deliver for introduction into interstate commerce any “new drug" unless the drug is the subject of an approved application. [21 USC. §355(a)]

1.2.1. The “application” established was a New Drug Application. Homeopathic drugs are not required to file New Drug Applications. The definition of a new drug does not include homeopathic drugs.

2. **Regulatory Background**

2.1. FDA Rulemaking Affecting Homeopathic Drugs 1938-2017

As a result of the 1962 “New Drug” amendments, FDA created at least six categories of pharmaceutical drugs for regulation by FDA:

Category #1: New Drugs - Drugs entering the market after the President signed the “New Drug” bill into law on October 10, 1962;

Category #2: Old Drugs (Prior Approved Drugs) - Drugs approved as safe but not approved as effective (the 1938 Act did not require proof of efficacy) between 1938 and 1962;

Category #3: Over-the-Counter Drugs - Drugs that are safe and effective for use by the general public without seeking treatment by a health professional;

Category #4: Exempted Drugs - Drugs that were, at any time prior to June 25, 1938, subject to the Food and Drugs Act of June 30, 1906, as amended are not “new drugs”;

Category #5: GRAS/E Drugs - Drugs that are generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof;

Category #6: Unapproved Drugs - Drugs that FDA allows to be marketed even though they do not have New Drug Applications (NDAs) approved by FDA.[45]
FDA has repeatedly identified and treated homeopathic drugs as unique and outside of the categories of allopathic drugs. Homeopathic drugs and homeopathic drug products that meet the criteria for inclusion in the HPUS also meet the criteria for categories 4, 5 and 6, none of which require approval by FDA as "New Drugs."

2.1.1. **Category #1: New Drugs -** Drugs entering the market after the President signed the "New Drug" Act into law on October 10, 1962. The unique nature of homeopathy—whose medicines are inherently safe, make up the second-largest system of medicines worldwide, have a strong following among American consumers, and are the fastest-growing non-pharmaceutical drug system of medicine—ensures that no sponsors of homeopathics will be required to seek to enter their products into the market through the New Drug Application (NDA) process. The unique structure of homeopathy makes such an undertaking conceptually, operationally, and practically impossible.

The 1962 law established that any prescription drug in Category #1 --- entering the market after the Kefauver-Harris bill became law—is a "new drug" that requires a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) in order to be legally marketed.

The 1962 law focused on the inherent safety problems of dangerous chemicals (pharmaceuticals) used to treat diseases by requiring proof that the benefits of the chemicals so used outweighed their risk and did not identify homeopathic drugs as new drugs.

2.1.2. **Category #2**: **Old Drugs (Prior Approved Drugs) -** Drugs approved as safe but not approved as effective (the 1938 Act did not require proof of efficacy) between 1938 and 1962.

The FD&C Act established that Category #2 drugs—drugs entering the market between the effective date of the 1938 Act and the effective date of the 1962 Amendments—need to be reviewed for proof of efficacy, which had not been required when they were originally approved. To accomplish this task, FDA established two programs. The first, the Drug Efficacy Study Implementation (DESI) review, was designed to address

[45] Unapproved drugs that sell on the market without approval of FDA include digitalis, nitroglycerin tablets, morphine concentrated solution, morphine sulfate solution, phenobarbital, carbinoxamine, pheniramine maleate and dexbrompheniramine maleate (in cough and cold combination drugs).Marketed Unapproved Drugs –Compliance Policy Guide Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER)September 19, 2011.https://www.fda.gov/media/71004/download.

prescription drugs. The second, the Over-the-Counter Drug Review, was designed to address over-the-counter drugs.

DESI Prescription Drug Review

Drug Efficacy Study Implementation (DESI) is a program begun by FDA in 1966 after the requirement in the 1962 Kefauver-Harris Drug Control Act that all drugs have substantial evidence of efficacy as well as being shown to be safe, became part of US law. The DESI program is intended to classify all pre-1962 drugs that were already on the market as either effective, ineffective, or needing further study. DESI evaluated over 3,000 separate products and over 16,000 therapeutic claims. By 1984, final action had been completed on 3,443 products; of these, 2,225 were found to be effective, 1,051 were found not effective, and 167 were pending.[46]

The drugs covered under DESI are those that have:

- been reviewed by the National Academy of Sciences/National Review Council (NAS/NRC)—on a contract from FDA— or

- entered the market without FDA approval because they are identical, related, or similar to those covered by safety-only FDA approvals.[47] This group represents an even larger number of drugs than those reviewed by NAS/NRC.

One of the early effects of the DESI study was the development of the Abbreviated New Drug Application (ANDA). DESI continues today (2020) as an FDA program, and many drugs remain neither upgraded to having substantial evidence of efficacy nor being removed from the market for lack of substantial evidence supporting efficacy.

All homeopathic drugs are available without NDAs or ANDAs at the minimum safe dilution defined by HPUS. Due to the unique nature of homeopathic drugs, the FDA contract with NAS/NRC did not include homeopathic drugs. All homeopathic drugs have been reviewed for safety and efficacy before listing in HPUS. Many products described as “Drug Products Labeled as Homeopathic,” in FDA’s proposed October 2019 Draft Guidance for FDA Staff and Industry, are not homeopathic and therefore have not been reviewed for safety and efficacy by HPUS.

2.1.3. **Category #3: Over-the-Counter Drug (OTC) Review -** FDA makes GRAS/E determinations for OTC drugs marketed under the OTC Drug Review.[48] FDA has not reviewed but deferred any homeopathic drug products under the OTC Drug Review because FDA categorized these products as a separate category and deferred consideration of them.[49]

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[46] https://en.wikipedia.org/wiki/Drug_Efficacy_Study_Implementation
https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs

[47] https://www.fda.gov/drugs/enforcement-activities-fda/drug-efficacy-study-implementation-desi

[48] Appendix #9: Over-the-Counter Drug Review, 21 CFR part 330.1.

[49] Appendix #10: Over-the-Counter Drug Review in 37 Fed. Reg. 92, 9466 (May 11, 1972) which establishes the FDA OTC monograph system and exempts homeopathic drugs

In 1972, FDA established the OTC Review to evaluate the safety and efficacy of OTC ingredients, doses, formulations, and labeling used in drugs available to consumers without a prescription.

At the initiation of the OTC review, then FDA Commissioner Charles C. Edwards, MD, stated that FDA intended:

. . . to build a permanent system offering all American consumers the best possible assurance that every over-the-counter drug... not only is safe and adequately labeled, but that it will do what the manufacturer claims it will do. . .”

FDA continues to embrace this standard of consumer protection today, 47 years later.[50] To conduct the review, which is still (2020) underway, FDA assembled panels made up of physicians, pharmacists, and other specialists. Each panel also included two non-voting members, one for industry and one representing consumers. Each panel was charged with examining one or more categories of OTC drugs such as cough and cold, antacids, laxatives, etc.

The panels heard testimony from scientists, consumers, and industry representatives. They reviewed scientific studies, reports, and other data, most of which was submitted by manufacturers and developed monographs for the category it was charged with. FDA sought comments on the draft monographs. FDA then analyzed the comments and issued a final monograph.

Paragraph 25 of FDA’s announcement of the OTC review said:

> The American Institute of Homeopathy requested that homeopathic drugs be excluded from the OTC review. Because of the uniqueness of homeopathic drugs, the Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete.[51]

FDA has historically and repeatedly taken the position that homeopathic drugs do not fall under the DESI or OTC review processes. The unique nature of homeopathy continues to exist today, and AFHC believes that homeopathic drugs should continue to be reviewed under a separate process. All homeopathic drugs and drug products meet the criteria of Categories 4, 5 and 6 below.

No homeopathic drugs require approval under the new drug application process or the over-the-counter drug review process. All homeopathic drugs are reviewed for safety and efficacy before being included in the HPUS.

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[50] https://www.chpa.org/FAQsOTCReview.aspx

[51] *Op. cit*., fn 49: Appendix #10: Over-the-Counter Drug Review in 37 Fed. Reg. 92, 9466 (May 11, 1972).

2.1.4. **Category 4**: **Exempted Drugs -** Drugs that were, at any time prior to June 25, 1938, subject to the Food and Drugs Act of June 30, 1906, as amended are not "new drugs."

The vast majority, if not 100%, of all homeopathic drugs on the market in 1962 were subject to the Food and Drugs Act of 1906. Since 1962, many drug products labeled as "homeopathic" have reached the market, some of which are homeopathic, and some of which have been mislabeled as "homeopathic." Drug products mislabeled as "homeopathic" are not exempted homeopathic drugs.

2.1.5. **Category 5: GRAS/E Drugs -** Drugs that are generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

The GRAS/E status of homeopathic drug products is established through the HPUS process. All homeopathic drugs in the HPUS are recognized as safe and effective by experts who are qualified by scientific training and experience to evaluate the safety and effectiveness of homeopathic drugs. The HPUS has ongoing procedures that engage qualified experts to determine which drugs qualify to be added to the HPUS.[52]

2.1.6. **Category 6: Unapproved Drugs -** FDA says, "The Agency's guidance document *Marketed New Drugs Without Approved NDAs, and ANDAs* (CPG 440.100 https://www.fda.gov/media/72007/download) permits some unapproved drugs to be marketed. Homeopathic drugs fit into this category. Because a drug is unapproved does not mean that it is illegal.[53]

2.2. Administrative Process Applied to Homeopathy: 2015 FDA Meeting to Consider Homeopathic Product Regulatory Framework

In 2015, FDA published a document in the Federal Register entitled "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing: A Proposed Rule by the Food and Drug Administration.[54] This document addressed homeopathic products.

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[52] *Op. cit.,* fn 9, Appendix #1: "Operation Plan for Adding Drugs to HPUS." Petitioners support the development of a robust third-party certifying system for managing the process by which drugs are accepted for inclusion in the HPUS. HPCUS is an example of such a third party.

[53] FDA says "The agency permits some unapproved drugs to be marketed if they are relied on by health care professionals to treat serious medical conditions when there is no FDA-approved drug to treat the condition or there is insufficient supply of FDA-approved drugs." https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs. A number of important drugs including digitalis, colchicine, nitroglycerin tablets, morphine concentrated solution, morphine sulfate solution, phenobarbital, chloral hydrate, carbinoxamine, pheniramine maleate and dexbrompheniramine maleate (in cough and cold combination drugs) sell on the market without approval of FDA.

[54] *Op. cit.,* fn 10, Appendix #2: 80 Fed. Reg. 16327, Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century. https://www.govinfo.gov/content/pkg/FR-2015-03-27/pdf/2015-07018.pdf

2.2.1. In April 2015, FDA held what it characterized as a two-day public "hearing" but which was, in fact, a two-day public meeting because it did not adhere to the public hearing rule-making requirements of the Administrative Procedures Act.[55] (See subsections 2.2.2 - 2.2.5 of this section).

2.2.2. Additionally, FDA's stated goal for this meeting was to obtain information and comments from stakeholders about the current use of homeopathic drug products and its regulatory framework for such products.

2.2.3. FDA did not announce that it was seeking information about drug products labeled as homeopathic or that it was seeking information about a risk-based approach to drug products labeled as homeopathic.

2.2.4. From these meetings, FDA developed an extensive record about homeopathy, but neither the announcement of these meetings nor the meetings themselves:

- resulted in the creation of a proposed rule,
- addressed risk-based enforcement policy for homeopathy, or
- responded to individual comments made in the meetings.

2.2.5. FDA characterized these meetings as a public hearing to seek input on its enforcement policies related to homeopathic product regulation. While FDA sought public input on its enforcement policies related to homeopathic drug products for the purpose of creating a proposed rule in an effort to better promote and protect public health, a proposed rule was not the result of these meetings. No rule was promulgated. Petitioners present this petition to re-start and complete the process initiated in the March 2015 meeting which announced a "Public Hearing: A Proposed Rule."

2.3. FDA Regulatory Policy Concerning Homeopathic Drug Products 2017-2019

2.3.1. As a result of the Agency's evaluation of thirty years of regulatory policy concerning homeopathic drug products (including the consideration of the broad and diverse public input and information obtained as a result of the public meeting held in 2015 concerning homeopathic drug products) FDA issued the Draft Guidance in December 2017, entitled, "Drug Products Labeled as Homeopathic, Guidance for FDA Staff and Industry."

2.3.2. In the title of this draft guidance, the Agency purports to address "Drug Products Labeled as Homeopathic," but in the body of the draft guidance, it Addresses "homeopathic drug products." As detailed in this petition, these are distinct from each other.[56]

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[55] For a review of rulemaking, see "A Brief Overview of Rulemaking and Judicial Review," Todd Garvey Legislative Attorney, Congressional Research Service March 27, 2017.

[56] *Op. cit*., fn 6: For example, in its 2019 Proposed Guidance, Drug Products Labeled as Homeopathic, the words "homeopathic drug product(s)" appear in lines 16, 21, 25, 54, 62, 69, 78, 79, 81, 88, 95, 97, 98,

2.3.3. The draft guidance detailed a risk-based enforcement policy, which had not been the announced purpose for the meeting or addressed in the meeting itself. FDA stated in its guidance that the purpose of the risk-based policy was for "prioritizing enforcement and regulatory actions for certain categories of homeopathic products that potentially pose higher risk to public health." The guidance did not say higher than what. Petitioners file this petition as an effort to assist the FDA in effectively addressing all "Drug Products Labeled as Homeopathic" rather than ineffectively addressing only "Homeopathic Drug Products."

2.3.4. Additionally, in its proposed guidance, FDA did not respond to the comments that were made at or in response to the 2015 meeting.[57]

2.3.5. As part of the Administrative Procedure Act, Petitioners request that FDA upholds the original stated purpose for the 2015 meetings by either adopting Petitioners' proposed regulation or by holding a proper public hearing in accordance with the Administrative Procedures Act to evaluate its proposed rule for homeopathic drug products and drug products labeled as homeopathic.

2.3.6. Integral to the petitioners' request is that if FDA applies a risk-based policy to homeopathic drugs and drug products labeled as "homeopathic," it will base such policy on generally accepted standards of risk analysis and set out how such a risk-based enforcement policy shall be applied to properly labeled and manufactured homeopathic drugs and homeopathic drug products, which pose very little, if any, risk as set forth in section F.3. of this petition.

2.4. **December 2017 Guidance "Drug Products Labeled as Homeopathic"**

The petitioners assert that the FDA was acting outside of the law, when in December 2017, FDA announced a proposed guidance for the regulation of drug products labeled as homeopathic. This proposed guidance reversed the 79-year history of the FDA's enforcement policy, adopted in accordance with the Food Drug and Cosmetic Act of 1938, which established Homeopathic Drugs as a unique category of drug products, and treated homeopathic drug products as inherently safe and unique and different from drugs in the United States Pharmacopeia and the United States Formulary.

While the proposed guidance was entitled "Drug Products Labeled as Homeopathic," the body of the proposed guidance addressed "homeopathic drug products."

2.4.1. **Conflict of Terms**

102, 107, 117, 122, 124, 138, 145,147,152, 155. A search for the words "Drug Product labeled as Homeopathic" found them only in the title and not in the body of the guidance. This dichotomy creates serious confusion for consumers, producers and practitioners.

[57] *Op. cit.*, fn 10, Appendix #2: 80 Fed. Reg. 16327, Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century. https://www.govinfo.gov/content/pkg/FR-2015-03-27/pdf/2015-07018.pdf

The uncertainty created by the use of the terms “drug products labeled as homeopathic” in the title and “homeopathic drugs” in the body of this proposed guidance, lies at the heart of the confusion that has followed the announcement of the proposed 2017 guidance “Drug Products Labeled as Homeopathic.”

2.4.2. **Change of Policy for Homeopathic Drugs**

- As defined in Section III of this petition “Background of Petition” under 2.1 and 2.2, “drug products labeled as homeopathic,” which may be improperly manufactured or mislabeled as homeopathic, are distinctly different from “homeopathic drugs,” which are *bona fide* homeopathic drugs, properly manufactured and labeled per HPUS.

- FDA has affirmed the unique status of homeopathic drugs as well. Specifically, on April 1, 1983, FDA finalized an amendment to a proposed regulation applying certain good manufacturing practice rules to drugs and commented on a petition from the American Association of Homeopathic Pharmacists (AAHP), saying:

  > “FDA has weighed all of the petitioners’ contentions and believes that most of the arguments are well-founded and that the petition should be granted. As explained in detail below, the Agency’s position is based on the following three factors: First, the Agency believes that granting the petition is entirely consistent with the Agency’s prior recognition of homeopathic drug products as unique entities. Second, the Agency is convinced that the benefits to be gained by enforcing the requirement are far outweighed by the potential increase in costs to the industry [and the homeopathic consumer added by petitioner AFHC] of conducting the active ingredient tests. **Third, the Agency believes that the quality controls required by the other portions of the CGMP regulations and the requirements of ‘The Homeopathic Pharmacopoeia of the United States’ are sufficient to ensure the quality of homeopathic drug products.”**[58] (Emphasis by Petitioners.)

- In this same document, FDA further explained:

  > “The third basis for granting this petition is the Agency’s belief that assurance of the quality of this class of drug products [homeopathic added by petitioners AFHC] can be achieved by applying other controls and standards. Although the Agency is cognizant of the homeopathic concept of potency, it is still important for manufacturers of homeopathic drug products to establish with a reasonable degree of certainty that finished products contain the drug substances claimed in the labeling, and at the claimed degree of attenuation. Nonetheless, **the Agency**

[58] *Op. cit.*, fn 39 : Appendix #7: 48 Fed. Reg. 64, 14004 (April 1, 1983) https://www.govinfo.gov/content/pkg/FR-1983-04-01/pdf/FR-1983-04-01.pdf

> **believes that this objective can be attained for these drug products by adherence to the other requirements of the CGMP regulations and to the quality and production standards of 'The Homeopathic Pharmacopoeia of the United States.'** (Emphasis by Petitioners AFHC.)
>
> "Accordingly, the agency tentatively has concluded that exempting homeopathic drug products from the required testing for identity and strength of their active ingredients will not diminish the overall quality of these drug products."[59]

- As part of a general withdrawal of 81 pending proposed regulations, FDA withdrew the proposed regulation in 2004. It did not reject the concept that homeopathic drugs are unique and different from conventional drugs. FDA continued to affirm that the proper manufacturing and labeling of products labeled as homeopathic is integral to ensuring safe homeopathic drugs. In note 11 of the withdrawal, FDA said:

> "There may be instances where testing of a homeopathic product for identity and strength of the active ingredients prior to release for distribution would be appropriate and consistent with protection of the public health. For example, in instances where a product includes an active ingredient that at certain levels could be toxic or otherwise pose a public health concern, finished product testing may be appropriate because the testing could identify a significant **manufacturing or labeling error**…requiring this testing when necessary to protect the public health is consistent with FDA's mandate…"[60] (Emphasis by Petitioners AFAC.)

- In 1987 FDA announced the CPG 400.400, which again stated the policy of FDA, that homeopathic drugs must be properly labeled and manufactured in order to be compliant:

> "Documentation must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients."
>
> "Homeopathic drug products must be manufactured in conformance with current good manufacturing practice, Section 501(a)(2)(B) of the Act and 21 CFR 211. However, due to the unique nature of these drug products, some requirements of 21 CFR 211 are not applicable."[61]

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[59] Ibid

[60] Appendix #11: 69 Fed. Reg. 227, 68834 (Nov. 26, 2004). https://www.govinfo.gov/content/pkg/FR-2004-11-26/pdf/FR-2004-11-26.pdf

[61] CPG Sec. 400.400 "Conditions Under Which Homeopathic Drugs May be Marketed"

- As a matter of policy until 2017, FDA recognized that good manufacturing practices and the HPUS combined were sufficient to ensure the safety and efficacy of homeopathic drugs and drug products, and it did not require homeopathic drugs to receive premarket approval or file a new drug application. There are other instances where homeopathic drugs are distinguished from drugs requiring an approved new drug application.[62] This policy remained in force until the announcement of the proposed 2017 guidance, "Drug Products Labeled as Homeopathic." FDA made this policy explicit in the various categories of drugs listed in Section F, Parts 2.1.1-2.1.6. For example, in 1972, when it announced its Over-the-Counter Drug Review (OTC) FDA said:

  > "The American Institute of Homeopathy requested that homeopathic medicines be excluded from the OTC review. Because of the uniqueness of homeopathic medicine, the Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete."[63]

- Another instance where FDA applied this policy to homeopathic drugs occurred when it excluded homeopathic drugs from its Drug Efficacy Study Implementation (DESI) Review (see Section IV, part 1.2.2). The DESI Review of prescription drugs that came on the market between 1938 and 1962 excluded homeopathic drugs because FDA saw them as part of a unique form of medicine. Recognizing homeopathy as a unique and separate category of medicine remained the policy of FDA until the proposed December 2017 guidance, reversing 80 years of the FDA's policies. Petitioners believe the FDA's policies over the last eighty years were consistent with the requirements of the law. Petitioners also believe that the proposed draft guidance of 2017/19 is not consistent with the requirements of the law.

2.5. **Withdrawal of Compliance Policy Guide 400.400**

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https://wayback.archive-it.org/7993/20190905164322/https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-400400-conditions-under-which-homeopathic-drugs-may-be-marketed

[62] Appendix #12: FDA's Statements of General Policy or Interpretation found in 37 Fed. Reg. 156, 16174 (Aug 11, 1972) https://www.govinfo.gov/content/pkg/FR-1972-08-11/pdf/FR-1972-08-11.pdf
The policy stated in the 1983 proposed and then withdrawn regulation implemented the principles of the FDA's 1972 Statement of General Policy or Interpretation. In 1972 FDA said: "In the enforcement of the Federal Food, Drug, and Cosmetic Act and other statutes, the Commissioner of Food and Drugs often must rely upon the results obtained by chemical, physical, and biological methods of analysis to demonstrate compliance or noncompliance with the statute and regulations. The methods of analysis used for this purpose may be implicit in the statute as in the case of the United States Pharmacopoeia, National Formulary, and the **Homeopathic Pharmacopoeia**, ***or*** **specified in an approved new-drug application** or supplied in a food or color additive petition. They may be promulgated in detail as in the case of the antibiotic regulations. In other cases, they may be incorporated by reference as with pesticide residue methods and many food standards." (Emphasis added by petitioners.)

[63] *Op. cit.*, fn 48, Appendix #9. Over-the-Counter Drug Review in 37 Fed. Reg. 92, 9466 (May 11, 1972) https://www.govinfo.gov/content/pkg/FR-1972-05-11/pdf/FR-1972-05-11.pdf

In May 1988, the Center for Drug Evaluation and Research (CDER) issued Compliance Policy Guide (CPG) 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed." As stated in the 1988 CPG, it "delineate[d] those conditions under which homeopathic drug products may ordinarily be marketed," including conditions regarding ingredients, labeling, prescription status, and current good manufacturing practice. In October of 2019, FDA withdrew CPG 400.400. The withdrawal of CPG 400.400 makes adopting a regulation for homeopathic drugs imperative since FDA no longer has either a regulation or a guidance on marketing homeopathic drug products which "delineate[s] those conditions under which homeopathic drug products may ordinarily be marketed,"

2.5.1. FDA's Reexamination of Its Enforcement Policies

In light of the growth of the consumer use of homeopathic drugs and as a consequence the growth of the homeopathic drug industry and passage of more than two decades since the issuance of CPG 400.400, FDA announced on March 27, 2015, that it was evaluating its regulatory framework for homeopathic drug products.[64] In April 2015, FDA held a public meeting[65] to obtain information and comments from stakeholders about the current use of homeopathic drug products, as well as the FDA's regulatory framework for such products.[66] FDA sought broad public input on its enforcement policies related to homeopathic drug products in an effort to better promote and protect the public health.

2.5.2. Neither the announcement of the 2015 meeting nor the meeting itself specifically addressed "Drug Products Labeled as Homeopathic," which was the title of the 2017 (revised in 2019) "Guidance for FDA Staff and Industry DRAFT GUIDANCE."

2.5.3. Petitioner has seen no information, including from FDA, that shows that properly labeled and manufactured homeopathic products have caused any harm. Possible harm caused by drug products improperly labeled as homeopathic and/or improperly manufactured, including inadequate process controls, raise significant concerns about the safety of drug products labeled as homeopathic. However, these drugs are not homeopathic drugs, do not become so just because they are labeled homeopathic, and by being labeled homeopathic violate labeling laws.

2.5.4. As a result of FDA's evaluation of its regulatory framework, including consideration of the information obtained during the 2015 public

[64] *Op. cit*. fn 10, Appendix #2: 80 Fed. Reg. 16327, "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century."
[65] ibid. https://www.federalregister.gov/documents/2015/03/27/2015-07018/homeopathic-product-regulation-evaluating-the-food-and-drug-administrations-regulatory-framework However no regulation was ever issues and the proceedings, held April 21 and 22, 2015, were treated as a meeting rather than a hearing under the Administrative Procedure Act.
[66] Docket No. FDA-2015-N-0540; available at https://www.regulations.gov/docket?D=FDA-2015-N-0540.

meeting[67] and the recent growth of alleged safety concerns associated with drug products labeled as homeopathic, FDA concluded that it is in the best interest of public health for it to issue a new guidance that applies a risk-based enforcement approach to drug products labeled as homeopathic consistent with the FDA's risk-based regulatory approaches generally. If FDA persists in applying a risk-based approach to homeopathic drugs and drug products, it must do so in a proper manner.

- First, FDA must apply a proper risk-based policy to all drug products labeled as homeopathic, as opposed to only homeopathic drug products as the proposed guidance appears to do, Applying a sound risk-based policy to all drug products labeled as homeopathic would demonstrate the inherent safety of properly labeled and manufactured homeopathic drug products while protecting the public from improperly marketed or manufactured drug products labeled as homeopathic.

- Second, for an FDA applied risk-based policy to be effective and not counterproductive, it must be applied evenhandedly across all areas of regulatory responsibility that FDA assumes including—but not limited to—food, all drugs, cosmetics, devices, supplements, etc. Again, an even-handed risk-based policy applied across the Agency responsibilities would demonstrate that homeopathic drugs and drug products fall into the lowest area of safety concern for all FDA regulated products.

3. **Risk-Based Policy**[68]

FDA has indicated its intention to apply a risk-based policy to homeopathic drugs and drug products labeled as homeopathic. If FDA does use a risk-based policy in regulating homeopathic drugs and drug products, petitioners petition the Agency to adopt a risk-based policy that complies with generally accepted risk analysis standards.

3.1. Homeopathic drug products are those that, as set out in the FD&C Act of 1938, meet the requirements for inclusion in the Homeopathic Pharmacopoeia of the United States (HPUS), its addendums or supplements. Products that are labeled as homeopathic and do not meet the requirements for inclusion in the Homeopathic Pharmacopoeia of the United States or its supplements[69] are misbranded under the FD&C Act of 1938. Absent a determination that any specific homeopathic drug is a new drug, or any specific homeopathic drug product is a new drug, FDA will treat all homeopathic drugs and drug products as generally recognized as safe and effective for their intended use (GRAS/E).

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[67] *Op. cit.*, fn 10: Appendix #2: 80 Fed. Reg. 16327, "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing." https://www.govinfo.gov/content/pkg/FR-2015-03-27/pdf/2015-07018.pdf

[68] *Op. cit.*, fn 11, Appendix #3: "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic."

[69] In CPG 400.400, FDA said, "Homeopathic Drug: Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopoeia of the United States (HPUS), an addendum to it, or its supplements."

3.1.1. The new drug amendments of 1962 apply only to prescription drugs, which are drugs prescribed for the cure, treatment, mitigation, diagnosis, or prevention of identified diseases at the direction of a qualified medical professional. Homeopathic drug products are used to treat individuals and address specific health situations at the time and place of their use under the guidance of a qualified practitioner. Homeopathic drugs are also used for "self-care" to cure, treat, mitigate, and prevent various self-limited diseases.

3.1.2. A limited number of Homeopathic drugs are identified in the HPUS as drug products dispensed only in consultation with a licensed or certified health-care provider to treat specific individuals for unique, personal situations/symptoms at the time and place of their use. Homeopathic drugs are drugs under the law, but they are not prescription drugs, and they are not "new drugs."

3.2. Many consumers use various types of "unapproved" drugs,[70] including homeopathic drugs. Homeopathic drugs, while subject to current good manufacturing practice and proper labeling regulations are not subject to premarket approval other than that provided by the HPUS and do not require a new drug application.

3.3. Homeopathic drug products have a record of exceptional safety.[71] FDA has said in its 2017/19 proposed guidance for drug products labeled as homothetic that it anticipates that most homeopathic drug products will fall outside the categories of drug products that FDA intends to prioritize for enforcement and regulatory action as described in Section V(5) below. All products labeled as homeopathic, which do not meet the requirements for inclusion in the Homeopathic Pharmacopoeia of the United States, its addendums or supplements fall into the category of drug products labeled as homeopathic that are misbranded under the FD&C Act of 1938 as amended and are not considered homeopathic drug products.

3.3.1. FDA recognizes homeopathic drugs currently listed in the Homeopathic Pharmacopoeia of the United States (HPUS) as GRAS/E. Petitioner proposes that FDA extend such recognition to homeopathic drug products newly listed in the HPUS when a system is established for reviewing products that enter HPUS that is recognized by an

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[70] *Op.cit*. fn 53: FDA says, "The agency permits some unapproved drugs to be marketed if they are relied on by health care professionals to treat serious medical conditions when there is no FDA-approved drug to treat the condition or there is insufficient supply of FDA-approved drugs." https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs. A number of important drugs including digitalis, colchicine, nitroglycerin tablets, morphine concentrated solution, morphine sulfate solution, phenobarbital, chloral hydrate, carbinoxamine, pheniramine maleate and dexbrompheniramine maleate (in cough and cold combination drugs) sell on the market without approval of FDA.

[71] Appendix #13: "The Safety of Homeopathy," Americans for Homeopathy Choice & Ronald W. Dushkin, MD and Ronald D. Whitmont, MD. https://homeopathychoice.org/app/uploads/2019/03/The-Safety-of-Homeopathic-Medicine-AFHC-Citizen-Petition-Supporting-Document-1.pdf.

independent standard reporting organization. Making that determination is not FDA's role.[72]

3.4. Application of Risk-Based Policy Approach to Homeopathic Drugs and Drug Products Labeled as Homeopathic

3.4.1. Petitioners seek a regulation that sets out how FDA will prioritize enforcement and regulatory actions for homeopathic drug products and drug products labeled as "homeopathic" marketed in the United States without FDA premarket approval.

3.4.2. FDA has announced that it generally intends to apply a risk-based enforcement approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic.

3.4.3. FDA has no agency-wide risk-based policy.

3.5. Applying a Risk-Based Policy to Homeopathic Drugs and Drug Products Labeled as Homoeopathic

3.5.1. FDA has developed a risk-based approach under which it says it intends to prioritize enforcement and regulatory actions involving certain products labeled as homeopathic that it says potentially pose a higher than acceptable risk to public health.

3.5.2. A Homeopathic drug is any drug with a single active ingredient that is included in or is certified as pending approval for inclusion in the Homeopathic Pharmacopoeia of the United States, including its supplements and addenda (HPUS) and contains no other active ingredients.

3.5.3. A "homeopathic drug product" is defined as a combination of more than one homeopathic drug, that is labeled as "homeopathic," and contains only active ingredients that are homeopathic drugs that are listed in HPUS, an addendum to it or its supplements, or is pending approval to be listed in the HPUS and applying for HPUS recognition.

3.5.4. The strengths or "potencies" of homeopathic drugs and homeopathic drug products are specified in terms of dilution and succussion and must contain diluents commonly used in homeopathic pharmaceutics and specified in HPUS, an addendum to it, or its supplements. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not considered homeopathic drugs or homeopathic drug products.

3.5.5. Drugs or drug products containing homeopathic ingredients that have not been reviewed, approved, or listed in HPUS, an addendum to it, or

[72] For example, the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) properly certified could be the source of information reported in the Homeopathic Pharmacopoeia of the United States. One way of achieving this could be to establish an independent certification and review process that allows HPUS to be recognized by FDA as an independent standard reporting pharmacopoeia.

its supplements, or are not pending approval for inclusion in the HPUS, or not eligible to apply for HPUS pending approval, are not considered homeopathic drugs or homeopathic drug products, even if they purport to contain homeopathic ingredients and are labeled as “homeopathic.”

3.6. **Enforcement and Regulatory Priorities: FDA’s Enforcement Policy**

3.6.1. FDA is not required, and generally does not expect, to give special notice that a drug product may be subject to enforcement action, however, absent a determination by FDA that any specific homeopathic drug is a new drug, or any specific homeopathic drug product is a new drug, FDA will treat all homeopathic drugs and drug products as generally recognized as safe and effective for their intended use (GRAS/E).

3.6.2. While subject to current good manufacturing practices and proper labeling regulations, homeopathic drugs do not require FDA premarket approval or a new drug application.

3.6.3. Any homeopathic drug or drug product labeled as homeopathic that is improperly manufactured or improperly labeled is misbranded and/or adulterated and therefore is subject to FDA enforcement action at any time.

3.6.4. In developing a risk-based approach to homeopathic drugs and drug products improperly labeled or manufactured as homeopathic, FDA has identified certain drugs and drug products labeled as homeopathic as potentially posing higher than acceptable risks to public health as follows:

- Products with reports of injury that, after evaluation, raise potential safety concerns. For example, MedWatch reports or other information submitted to FDA can indicate or signal a potential association between the product and an adverse event, medication errors, or other safety issues.

- Products that contain or purport to contain ingredients associated with potentially significant safety concerns. For example, potentially significant safety concerns are raised by products that contain or purport to contain:

    - An infectious agent with the potential to be pathogenic;

    - A controlled substance, as defined in the Controlled Substances Act, 21 USC. 167 812;

    - Multiple ingredients that, when used in combination, could result in possible interactions, synergistic effects, or additive effects of the various ingredients; and,

  - Ingredients that pose a risk of toxic or other adverse effects, particularly when the ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are not adequately controlled in the manufacturing process.

- Products for routes of administration other than oral and topical. For example, injectable drug products and ophthalmic drug products, in general, pose a greater risk of harm to users because the routes of administration for these products bypass some of the body's natural defenses. In particular, contaminated injectable and ophthalmic products can pose serious risks to the patient. However, adequately sterile, contamination-free, and properly produced injectable and ophthalmic homeopathic products are not high risk and have not been reported to cause any harm because of the unique nature of the dilute homeopathic substances.

- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions. Unapproved products for serious and/or life-threatening diseases or conditions raise public health concerns, in part, because they may cause users to delay or discontinue medical treatments that have been found safe and effective through the new drug application (NDA) or biologics license application (BLA) approval processes.

- Products for vulnerable populations. For example, patient populations such as immunocompromised individuals, infants and children, the elderly, and pregnant women may be at greater risk for adverse reactions associated with a drug product, even if it contains only small amounts of an ingredient, due to the varying ability of individuals in these populations to absorb, metabolize, distribute, or excrete the product or its metabolites. These populations may also be at greater risk of harm as a result of foregoing the use of medical treatments that have been found safe and effective through the NDA or BLA approval processes or under the OTC Drug Review. Homeopathic remedies are unique in their safety and have a low risk of adverse reactions. They are, therefore, appropriate for these vulnerable populations. It is generally thought that pharmaceutical drugs pose a higher risk in these populations. However, extensive research has shown homeopathic drugs to be safe and appropriate for these vulnerable populations without any undue risk. The most common potencies ("dilutions") for these routes of administration and for vulnerable populations are at 10-5 or higher and don't pose an unacceptable risk.

- Products with significant quality issues. For example, products that are contaminated with foreign materials or objectionable microorganisms, and/or are made in facilities with significant deviations from current good manufacturing practice, pose a significant safety risk to patients.

3.7. Criteria for Applying Risk-Based Policy[73] to Properly Labeled Homeopathic Drugs and Drug Products Improperly Labeled as Homeopathic

3.7.1. Americans for Homeopathy Choice (AFHC) Agrees with and supports the American Association of Homeopathic Pharmacies (AAHP) when it says it:

> "…agrees that FDA should use its limited enforcement resources in a manner that maximizes the public health. Accordingly, AAHP supports the use of a risk-based enforcement policy. In fact, that is the standard FDA has applied in practice since CPG 400.400 was adopted in 1988. However, by revoking CPG 400.400, FDA is eliminating the guidance needed to help industry and FDA personnel recognize compliant products. The proposed criteria for enforcement action priority are sufficiently vague that both enforcement and compliance will be compromised and become an area of uncertainty. In short, FDA is muddying the waters rather than clarifying them.
>
> "AAHP believes that FDA's risk-based approach should include some of the important criteria in CPG 400.400 not found elsewhere in Agency guidance or regulations. This approach would both focus FDA's enforcement resources where they are needed and provide industry, FDA personnel, and the public with the guideposts needed to market safe and properly labeled and manufactured products. Since FDA itself said that the proposed guidance would not impact many of the homeopathic drugs on the market, the Agency has an obligation to assure that products sold as homeopathic are manufactured and marketed properly."

American for Homeopathy Choice, in order to advance the effective use of risk- based policy for homeopathic drug and drug products labeled as homeopathic, petitions the FDA to recognize the low-risk potential of properly labeled and properly manufactured Homeopathic Drugs and adopt the following criteria for the application of Risk-Based Policy.

3.7.2. The formal establishment of homeopathy as a medical specialty marked the first time in modern history that any form of medicine prioritized both a risk-based and an evidence-based system of therapeutics. The system of homeotherapeutics was based on, and demanded, a rigorous approach to both safety and therapeutic efficacy. Currently, each homeopathic drug in the Homeopathic Pharmacopoeia of the United States (HPUS) complies with human testing standards that rigorously define both safety and clinical efficacy. Each drug in HPUS has, by definition, met the criteria of both risk-based and evidence-based study with respect to the entire body in each and every organ system.

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[73] *Op. cit.,* fn 11, Appendix #3: "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic."

3.7.3. Not only have homeopathic drugs undergone thorough risk-based and evidence-based analyses before they are ever recommended, prescribed, or marketed, but homeopathic drugs have first pioneered and then set the standard for this process for more than two centuries. If this process were adopted and adapted by the rest of the pharmaceutical drug industry, safety and efficacy standards could be dramatically improved across the entire field of medicine.

3.7.4. Homeopathy is the safest form of medicine in the world today, in part, because every single drug in HPUS has been identified, studied, and tested in healthy people, a requirement that has yet to be applied to any conventional drugs.

3.7.5. A tangible result of this safety testing is demonstrated by the fact that there is no evidence that homeopathic drugs, when properly labeled and manufactured and taken as prescribed, have ever caused harm, disability, or death.

3.7.6. FDA, in its wisdom, has followed the path laid out by Congress and repeatedly affirmed that homeopathic drugs are not only UNIQUE, but they are inherently SAFE.

G. Conclusion

Petitioners respectfully urge the Commissioner to:

- **Adopt the Proposed Regulation set forth in section A of this petition**.

- **Properly Labeled Homeopathic Drug Products:** Recognize as safe and effective homeopathic drugs that are properly manufactured and labeled and listed in, or formally pending approval for listing in, the Homeopathic Pharmacopoeia of the United States and its supplements and addendums (HPUS).

- **Drug Products Improperly Labeled as Homeopathic:** Prohibit any drug product not listed in, or formally pending approval for listing in, the Homeopathic Pharmacopoeia of the United States or its supplements or addendums from using the term homeopathic in any form that states or implies that the product is homeopathic.

- **Homeopathic Drug Product Manufacturing:** Ensure that any drug product listed in, or formally pending approval for listing in, the Homeopathic Pharmacopoeia of the United States and its supplements and addendums is manufactured in accordance with the determinations of the HPUS and the Good Manufacturing Practices of the United States Food and Drug Administration (FDA).

- **Risk-Based Policy:** If the FDA applies a risk-based policy to homeopathic drug products and drug products labeled as “homeopathic,” ensure that such risk-based policy is formulated and applied with generally accepted standards and procedures of risk assessment.

- **Request for Public Hearing:** Petitioners request that, if the Agency fails to grant this petition, it holds a public hearing in accordance with the procedures of the Administrative Procedures Act to consider the contents of this petition.

III. Environmental Impact

We claim categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34 of this chapter or an environmental assessment under 25.40 of this chapter. And,

An environmental impact statement is not required for this petition because homeopathic drugs already have their own system of oversight under the law. As discussed extensively in this petition, homeopathic drugs comply with and conform to the law. No new food, color additive drug, or any type of medical device is being requested in this petition.

IV. Economic Impact

1.1. Economic impact information will be submitted upon request of the Commissioner.

V .Request for Hearing

Petitioners request that the Agency if it fails to grant this petition, hold a public hearing on this matter. If the FDA chooses to hold a hearing rather than to adopt Petitioners' proposed regulation, this hearing should address the application of a risk-based enforcement policy to homeopathy and the status of homeopathy under the Food Drug & Cosmetic Act.

VI. Incorporate by Reference

This petition incorporates by reference a) all entries into the docket, including all announcements and documents supporting and submitted to the hearing record for the April 2015 hearing/meeting on homeopathy; b) all entries into the docket, including all documents and hearing records relating to the December 2017 proposed guidance on drug products labeled as homeopathic; c) all entries into the docket, including all documents related to and public record of Americans for Homeopathy Choice documents related to its 2018 petition; d) all entries into the docket, including all documents related to and public record of FDA's October 2019 proposed draft guidance.

VII. Identifying Information

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VIII. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully Submitted,

5 June 2020

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Appendices

Appendix #1: "Operation Plan for Adding Drugs to HPUS"

Appendix #2: 80 Fed. Reg. 16327, "Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century: Public Hearing"

Appendix #3: "A Proposal by Americans for Homeopathy Choice (AFHC): for the Application of FDA Risk-Benefit Policy to Homeopathic Drugs and Drug Products Labeled as Homeopathic"

Appendix #4: "Supplements to the Homeopathic Pharmacopeia of the United States"

Appendix #5: "Limitations of FAERS Database"

Appendix #6: "Epidemic Infectious Diseases, Public Health and Homeopathy," Andre Saine, ND

Appendix #7: 48 Fed. Reg. 64, 14004 (April 1, 1983) https://www.govinfo.gov/content/pkg/FR-1983-04-01/pdf/FR-1983-04-01.pdf

Appendix #8: "Homeopathic Monographs Added to the Homeopathic Pharmacopoeia

Since 2000"

Appendix #9: "Over-the-Counter Drug Review," 21 CFR part 330.1

Appendix #10: "Over-the-Counter Drug Review" in 37 Fed. Reg. 92, 9466 (May 11, 1972)

Appendix #11: 69 Fed. Reg. 227, 68834 (Nov. 26, 2004)

Appendix #12: "FDA's Statements of General Policy or Interpretation" found in 37 Fed. Reg. 156, 16174 (Aug 11, 1972) https://www.govinfo.gov/content/pkg/FR-1972-08-11/pdf/FR-1972-08-11.pdf

Appendix #13: "The Safety of Homeopathy," Americans for Homeopathy Choice, and Ronald W. Dushkin, MD and Ronald D. Whitmont, MD