AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

4797 13 OCT 18 A9:51

October 17, 2013

Via Overnight Mail

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam:

The American Herbal Products Association (AHPA) submits this Citizen Petition pursuant to 21 C.F.R. § 10.30. AHPA is a trade association that represents companies that market herbs, herbal and botanical products, and other health-related products, including conventional foods, dietary supplements, and personal care products, regulated by the U.S. Food and Drug Administration (FDA). AHPA members are committed to compliance with the Federal Food, Drug, and Cosmetic Act (Act) and FDA's implementing regulations. The most recent and most complex regulations affecting AHPA members are those establishing current Good Manufacturing Practice (cGMP) for the manufacturing, packaging, labeling, or holding of dietary supplements.[1]

As AHPA has observed the implementation of the dietary supplement cGMP regulations over the past six years, it has become aware that inspectional observations issued on Form FDA-483 (483) do not normally inform recipients of the specific FDA regulation or regulations relevant to each observation. Specifically, the observations do not cite to, or use specific wording from, FDA regulations. AHPA understands that 483s lack such information because internal Agency policy directs investigators (1) not to disclose the regulatory bases for their observations and (2) to use standardized observation language that does not quote or otherwise disclose the relevant regulatory provisions on which investigators base their observations. As a result, when a firm receives a 483, it may not know what regulation FDA considers to be applicable to the observation. Inclusion of such information would assist the regulated industry in coming into compliance with FDA regulations and thereby promote the rationale underlying their promulgation.

AHPA submits that, by directing investigators to omit from 483 inspectional observations language from or citations to the relevant cGMP regulations, and apparently not to provide such information during close out conferences with management, FDA

[1] *See* 21 C.F.R. Part 111.

2013-8420 CP

FDA-2013-P-1291

forces industry members to play an unnecessary regulatory guessing game. This slows resolution of compliance issues and undermines Agency transparency. That this policy does not appear to further any Agency or public health interest also supports its abandonment.

Accordingly, AHPA submits this Petition to request that the Commissioner of Food and Drugs revise the Inspections Operations Manual (IOM) to require that Agency investigators include references to the underlying cGMP regulations in relation to each cGMP-related observation listed in 483s issued to conventional food and dietary supplement facilities.

I. Action Requested

AHPA respectfully requests that the Commissioner of Food and Drugs:

- formally rescind FDA's policy of prohibiting Agency investigators from quoting or citing the cGMP regulations upon which they base their inspectional observations within 483s issued to conventional food and dietary supplement facilities; and

- revise the IOM to expressly require that 483s issued to conventional food and dietary supplement facilities reference each cGMP regulation to which the Agency investigator's listed observations relate.

II. Statement of Grounds

A. AHPA and CGMP Background

AHPA is the only national trade association focused primarily on herbs and botanicals and herbal products. AHPA's mission is to promote the responsible commerce of herbal products, to maintain and improve market opportunities for companies that sell herbs, herbal and botanical products, and other health-related products, and to ensure that consumers continue to enjoy informed access to a wide choice of goods. Founded in 1982, AHPA is the oldest of the non-profit organizations that specialize in service to the herbal industry. It is the voice of the herbal products industry and the recognized leader in representing the botanical trade.

Most of AHPA's 300 members conduct FDA-regulated activities, such as manufacturing, packing, labeling, or holding conventional foods or dietary supplements, and thus most must comply with FDA's cGMP regulations for these product categories.[2] Many are also small businesses that have had to comply with FDA's dietary supplement cGMP regulations for only about three or four years, depending on the size of the

[2] *See* 21 C.F.R. Parts 110 & 111.

business.[3] These regulations are highly detailed and complex. The dietary supplement cGMP regulations remain relatively new to AHPA member companies, and FDA's approach to interpreting and enforcing the regulations has continuously evolved. AHPA members that manufacture, process, pack, or hold conventional foods or dietary ingredients will soon face a similar learning experience with respect to the hazard analysis and preventive control requirements imposed by the FDA Food Safety Modernization Act, which FDA has proposed to implement by modifying and supplementing the existing food cGMP regulations.[4]

B. Regulatory Background

In enforcing the Act and its implementing regulations, FDA conducts inspections of food and dietary supplement establishments. These inspections focus on compliance with the applicable cGMP regulations, which set forth requirements for practices designed to ensure that: (a) food is manufactured, processed, packed, and held under sanitary conditions; (b) the food is safe, clean, and wholesome; and, in the case of dietary supplements, (c) the product contains what the manufacturer intends. FDA's IOM explains the procedures Agency investigators must follow when conducting inspections of these facilities pursuant to section 704 of the Act.

At the conclusion of an inspection, the FDA investigator will notify the establishment's top management of any "significant objectionable conditions, relating to products and/or processes, or other violations of [the Act] or related Acts" via a standard form, the 483.[5] The IOM directs an investigator to issue a 483 when, in his or her judgment, the conditions or practices observed indicate that one or more products have been "adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health."[6] The IOM further instructs that investigators should "cite factual observations of significant deviations from" applicable statutes and regulations.[7] While each observation represents a "deviation from" a specific legal requirement or prohibition, the IOM forbids investigators from identifying the applicable regulations in 483s. The IOM states, "Do not quote Regulations (e.g.,

---

[3] *See* 72 Fed. Reg. 34,752, 34,752 (June 25, 2007) (stating that companies with 20-499 employees and companies with fewer than 20 employees had until June 25, 2009, and June 25, 2010, respectively, to comply with FDA's dietary supplement cGMP regulations).

[4] *See* 78 Fed. Reg. 3646 (Jan. 16, 2013).

[5] *See* IOM § 5.2.3 (2013). The Act itself requires the issuance of a "report" that sets forth "any conditions or practices observed by [the investigator] which, in his judgment, indicates that any food . . . in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 704(b).

[6] IOM § 5.2.3 (2013).

[7] IOM § 5.2.3.2 (2013).

specific CFR sections) when listing items."[8] AHPA also understands that, in general, investigators likewise decline to orally identify the specific regulations that the listed conditions or practices purportedly violate. Further, AHPA understands that, at the time they present 483s to facility management, investigators have (or have ready access to) this information.[9]

C. Argument

When advising a member of the regulated industry of inspectional observations that may constitute violations of law, FDA investigators should identify the specific legal requirement, e.g., cGMP regulation, with which the firm must come into compliance.

1. Citing Regulations in 483s Would Promote Understanding, Compliance, and Transparency

Including references to the relevant cGMP regulations for each 483 inspectional observation would facilitate discussion about what specifically the Agency believes the firm must comply with to satisfy the law. Any business, especially small businesses still trying to master and keep current with the dietary supplement cGMP regulations and their implementation by FDA, would benefit from receiving as much information as possible about the regulatory basis of each 483 observation.[10] Once the new regulations implementing FSMA's hazard analysis and preventive control requirements take effect, the same would be true for small (or other size) businesses trying to comply with those regulations.[11] In each case, the risk of confusion would be meaningful due to the relative novelty and complexity of the regulations. Directing facility management to the specific

---

[8] IOM § 5.2.3.3 (2013). This approach contrasts starkly with that of the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS). *See* FSIS Notice 42-07 (July 7, 2007) (directing FSIS inspection program personnel to "cite the specific regulations with which the establishment has failed to comply" when documenting inspectional observations in noncompliance records) (Exhibit 1).

[9] The software inspectors use to prepare 483s indexes specific regulatory citations for future use by the Agency. *See* FDA, Inspectional Observations and Citations, http://www.fda.gov/ICECI/EnforcementActions/ucm250729.htm#A_Short_Description_of_Citations (last updated May 25, 2011) ("Citations are maintained in a database and are reviewed, edited and updated on a periodic basis. Citations relate to a Code of Federal Regulations (CFR) reference, and there may be many citations for a single CFR reference. To create an FDA Form 483, citations are selected from the pre-established system or database. The Long Description is entered into the FDA Form 483, ensuring uniformity of presentation, then specific information related to the observation may be entered, and the citations may be ranked by significance on the 483.").

[10] Based on survey responses that identified employee data discussed in the preamble to FDA's Final Rule, approximately 92% of dietary supplement manufacturers have fewer than 500 employees and therefore qualified as "small businesses" for purposes of the phased-in cGMP compliance policy. More than half of these "small businesses" qualified as "very small businesses" (i.e., employed fewer than 20 employees). *See* 72 Fed. Reg. at 34,921.

[11] FDA estimates that approximately 97,169 conventional food facilities would be part of a "small business" (i.e., a business employing fewer than 500 employees). *See* 78 Fed. Reg. at 3701.

regulations underlying observations would inform internal decisions about corrective actions. Management could thereafter more promptly determine the type of corrective action needed to satisfy the relevant legal requirement.

Lack of knowledge of the legal basis for the observation may delay implementation of a corrective action that satisfies the Agency's concerns. Understanding the legal basis for each inspectional observation will allow a facility to develop and implement corrective actions that comprehensively address the underlying requirement. In addition, if management does not know why the investigator included an observation and the specific regulation to which it relates, the firm may waste valuable time trying to divine FDA's legal theory rather than planning and implementing a corrective action that brings the establishment into compliance with the regulation at issue. Misidentification of the regulation would likewise delay implementation of an appropriate corrective action. Accordingly, citing the regulation underlying each 483 observation should improve the quality of and turnaround time for industry responses, thereby furthering FDA's public health mission.

Identifying the cGMP bases for 483 observations would also improve FDA's transparency.[12] While it does not appear that the Agency's ongoing Transparency Initiative has focused on this issue, changing the 483 policy would be consistent with the principles of transparency and open government. If a regulator seeks voluntary compliance with highly technical regulations, at a minimum, it should identify the specific provision with which it seeks compliance. Doing so would promote understanding of how the Agency applies and interprets the regulations it enforces, which FDA seems to accept as critical to an effective, efficient, and transparent regulatory system. In particular, FDA has released inspection citation data sets that list both the written observations and the corresponding regulatory provision.[13] According to the Agency, FDA released these data sets to "improve the public's understanding of how the FDA works to protect the public health," "provide the public with a rationale for the Agency's enforcement actions," "help to inform public and industry decision-making," and "help to encourage compliance."[14] Providing regulatory citations in 483s would similarly improve transparency, understanding, and compliance.

2. Declining to Identify Regulations in 483s Does Not Further Agency Interests

The IOM does not explain FDA's reasoning for withholding references to specific cGMP regulatory provisions in 483s. However, the policy does not appear to further any Agency interest that would justify its negative impacts on understanding, compliance, and transparency. If FDA's policy stems from a concern about maintaining flexibility for

[12] *See* FDA Transparency Initiative Website, http://www.fda.gov/AboutFDA/Transparency/default.htm (last updated Sept. 17, 2013).

[13] *See* FDA Inspections Citations, http://www.fda.gov/ICECI/EnforcementActions/ucm346077.htm (last updated Apr. 3, 2013).

[14] *Id.*

future enforcement actions (e.g., that somehow FDA would "waive" the ability to rely on an omitted regulatory provision in a subsequent enforcement action), such a concern appears to be unfounded. Moreover, the policy appears inconsistent with FDA's approach to Warning Letters, which include regulatory citations in their allegations.

483s are the mechanism FDA has chosen to comply with the statutory requirement that it inform establishments of certain violative conditions found during inspections. However, 483s do not have any legal status and, like Warning Letters, they are not pre-requisites to legal action the Agency might wish to take. Citing cGMP regulations in a 483 would not prevent the Agency from later asserting that a specific condition or practice observed violated some other provision of law.[15] Similar to the approach FDA takes in Warning Letters,[16] the Agency could include in 483s language expressly reserving the right to base future enforcement actions on grounds other than those cited. FDA does not appear to believe that failing to include every possible violation in a Warning Letter ties the Agency's hands. The same analysis would apply to cGMP regulations were FDA to cite them in 483s.

Citing the regulations to which 483 observations relate also should not create any additional work for investigators or prolong the inspection process. As discussed above, AHPA understands that, in preparing 483s, investigators have (or have ready access to) the underlying cGMP regulatory citations. Granting the relief requested should not require the expenditure of any additional Agency resources. Rather, it may increase the efficiency of the 483 response process, resulting in FDA's receiving higher quality responses sooner and reducing the number of Warning Letters the Agency must prepare due to unsatisfactory 483 responses.

3. Identifying Regulations in 483s Would Harmonize the IOM and RPM

Citing the regulatory provisions to which 483 observations relate would also harmonize a significant conflict between the IOM and FDA's Regulatory Procedures Manual (RPM). Specifically, the RPM's "prior notice" policy generally requires that the Agency "afford individuals and firms an opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of an enforcement action."[17] FDA's Regulatory Procedures Manual (RPM) describes the principle underlying the policy as follows:

---

[15] *See, e.g., United States v. 789 Cases, More or Less of Latex Surgeons' Gloves . . .*, 799 F. Supp. 1275, 1296-1297 (D.P.R. 1992) (discussing precedent establishing why "Claimant's argument that it did not receive pre-seizure notice or have an opportunity to correct violations is not a defense to the charge of adulteration").

[16] *E.g.*, Warning Letter to Country Bakery LLC (Aug. 5, 2013), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm364450.htm ("The above violations are not intended to be an all-inclusive statement of violations that exist in your facility.").

[17] RPM § 10-2-3 (2012).

> . . . [A] basic principle of FDA's enforcement policy is the belief that the majority of persons will voluntarily comply with the law ***when given information as to what is required, what violations appear to exist,*** and, in the case of violations of regulatory significance, that failure to comply may result in the initiation of enforcement action.[18]

While FDA's "principal means" of providing prior notice is the Warning Letter, the policy does contemplate providing such notice via the less formal 483.[19] Whether a particular 483 may provide "prior notice" depends on its "adequacy."[20] The RPM requires that the 483 "adequately identif[y] the violative conduct, condition, practice or product."[21] Given the policy's underlying principle, a 483 cannot "adequately identify" a firm's "violative conduct, condition, practice or product" unless it identifies the precise legal basis for the alleged violation. To wit, the 483 must provide "information as to what is required" and "what violations appear to exist."

By its own terms, the RPM's "prior notice" policy requires that 483s identify specific regulatory violations in order to provide adequate notice. As the IOM prohibits investigators from providing such notice in a 483, however, the RPM inaccurately states that a 483 could provide prior notice under FDA's policy. Revising the IOM to require that 483 observations cite the regulatory provisions to which they relate would harmonize otherwise conflicting FDA policies on this point.

D. Conclusion

For the reasons discussed above, FDA's policy of prohibiting investigators from including references to regulatory provisions in 483s needlessly obstructs the compliance process. Abandoning that policy in favor of one requiring investigators to cite the cGMP regulations to which their 483 observations relate should improve the quality of 483 responses, further the Agency's transparency goals, and increase FDA's flexibility in cases where 483s fail to yield voluntary compliance. AHPA respectfully requests that the Commissioner grant the relief requested herein.

III. Environmental Impact

Petitioner claims a categorical exclusion from the requirements of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.30.

---

[18] RPM § 10-2-2 (2012) (emphasis added).

[19] RPM § 10-2-4 (2012).

[20] *See* RPM § 10-2-3 (2012). AHPA does not concede or suggest that including information in a 483 would have any effect on a subsequent legal proceeding. As stated therein, 483 observations "do not represent a final agency determination regarding" a firm's compliance.

[21] RPM § 10-2-3 (2012).

IV. Economic Impact

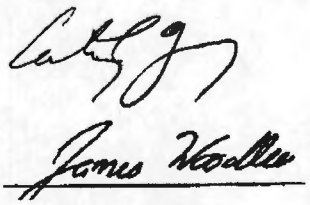
An economic impact statement will be submitted if requested by the Commissioner, pursuant to 21 C.F.R. § 10.30(b).

V. Certification

The undersigned certify 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 Petitioner which are unfavorable to the Petition.

Respectfully submitted,

Michael McGuffin
President, American Herbal Products Association
mmcguffin@ahpa.org
8630 Fenton Street, Suite 918
Silver Spring, MD 20910
(301) 588-1171 x201



Anthony L. Young
James W. Woodlee
Kleinfeld, Kaplan and Becker, LLP
General Counsel, American Herbal Products Association
ayoung@kkblaw.com
wwoodlee@kkblaw.com
1140 Nineteenth Street, N.W., Suite 900
Washington, DC 20036
(202) 223-5120