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BY FEDERAL EXPRESS

April 22, 2020

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
W051 / Room 6133

Frances Gail Bormel, RPh, JD
Director, Division of Prescription Drugs
Center for Drug Evaluation and Research
W051 / Room 5184
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Citizens Petition Requesting Evaluation of Ingredients Proposed for Functional Uses for Inclusion on the Bulk Ingredient Compounding List, Revision of FDA Final Rulemaking "List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act" and other relief.
Second Meeting Request | Filed in Docket FDA-2019-P-1351

Dear Dr. Woodcock and Ms. Bormel:

In response to your January 8, 2020 letter denying our request for a meeting to address the issues raised in the above-referenced Citizens's Petition, let me first note that we realize that Agency resources are urgently focused on addressing the COVID-19 pandemic and that travel and meetings need to be deferred as well. I write nonetheless because we wish to ensure that a decision on our Citizen's Petition is not be reached without FDA first meeting with Petitioners. Given the complexity of the issues involved, the extent to which FDA's regulatory approach directly affects Petitioners' professional practices and their patients, and continuing fundamental differences in approach that do not appear to have been appreciated or taken into account by the Agency, we believe a face-to-face discussion would be highly productive. The FDA's decision to proceed with publication of the proposed denial of 26 ingredients upon rationales to which we

took extensive exception in our Petition[1] puts us on notice that the Agency has not taken our concerns into account.

We find the statement that FDA does not ordinarily meet with petitioners to be puzzling and hard to countenance. We are aware of a number of similar instances in which such meetings have taken place, including, for example, with Petitioner Americans for Homeopathic Choice on that issue. On the compounding matter, we have been present at several meetings with FDA beyond the professional and industry listening sessions. Now postured as a petition, the regulations noted below are in fact written to favor FDA meetings with petitioners. We also suggest it would be vital to a demonstration by the Agency of an effort to hear the concerns of a significant body of professionals whose patients are adversely affected by FDA's actions.

As we have nominated a number of the ingredients that have been reviewed and rejected using the process to which our Citizen Petition raises objections, we are essentially sponsors seeking approval of compounded ingredients. The FDA routinely meets with sponsors of pharmaceutical and other applicants, a matter directly written into law, *see for e.g.*, 21 U.S.C. § 355(5)(B) ("The Secretary *shall* meet with a sponsor of an investigation or an applicant for approval for a drug .... [in this case] regarding design...") (emphasis added) and Guidance Documents. *See for e.g.*, Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry DRAFT GUIDANCE (December 2017). While we are not sponsors under the meaning of these provisions, our need to address the FDA's action arises solely because the Agency's interpretation of the DQSA required nominations defending long-used ingredients without formally providing comparable meeting opportunities. That should not lead to a difference in the willingness of FDA staff to engage in constructive dialog. The issues we are raising concern barriers to ingredient access the Agency has itself raised to which we have had to respond rather than efforts to obtain approval for novel ingredients. Our Citizen Petition directly raises the issue that pharmaceutical products for which PDUFA fees have been paid are being given a preferred market position over compounded drugs without a scientific or rational policy basis. To reject a meeting with us when it would be clearly available to the sponsor of a pharmaceutical drug seems further evidence that the concerns raised in our petition are in fact accurate.

The Agency position on meeting with us is directly inconsistent with the Agency's own

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[1] Petitioners submitted comments on that proposed rule; "Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, Docket No. FDA–2018–N–4845," which raised substantial discussion and provided scientific evidence of the safety and effectiveness of ingredients that were denied, a submission we hope will be taken into account both on that Proposed Rule and upon our Citizen's Petition.

regulations; 21 C.F.R. § 10.30(h) expressly provides that "[i]n reviewing a petition the Commissioner may use the following procedures: (1) Conferences, meetings, discussions, and correspondence under § 10.65." That provision states at section (a) that "meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner." 21 C.F.R. § 10.65(h). Such meetings are not only allowed, but the regulation further states at 21 C.F.R. § 1065(c) that "Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. *FDA will make reasonable efforts to accommodate such requests.*" (Emphasis added). The regulation proceeds to provide detailed instructions for how such meetings regarding petitions should occur, which seems contrary to a position that such meetings are not taken. The regulation expressly states at 21 C.F.R. §10.65(d) that: "*FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency.*" (Emphasis added). I can find no authority, source or evidence of the practice to which the Agency refers when it writes that the Agency's "general policy is not to meet with Petitioners, but instead, to rely on the publicly available information contained in the Petition docket."

While we appreciate the Agency's caution about process, any such concern is addressed, at least in part, in 21 C.F.R. § 10.65(e) which provides that a transcript be prepared to memorialize the discussion so that there is a proper record. The statement that you are limited to the public record to resolve a petition appears contrary to the regulations, policies and practice addressed in this letter.

As noted in our initial letter, when circumstances allow and it becomes sensible to arrange a meeting, our goal would be a substantive discussion in which we bring a small group of practicing physicians, pharmacists, researchers, attorneys and subject matter experts to ensure that the issues we raised in the Petition might be more fully appreciated. We believe that the Agency's legitimate concerns for safety and effectiveness can be addressed while leaving important treatment options intact and that a working meeting with the professions involved would serve the public interest.

Sincerely,

Alan Dumoff

Copies to on next page

cc: VIA US MAIL
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Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research
WO 51/ Rm 6276

Stacy Cline Amin
Chief Counsel
US Food and Drug Administration

VIA E-MAIL
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Michael J. Cronin, ND, Coordinator, Integrative Medicine Consortium (IMC)

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Aaron Lopez, Consultant, Medisca

Ron McGuff, President, McGuff Compounding Pharmacy Services, Inc. (MCPS)

Michael D. Levin, BA

U.S. FOOD & DRUG ADMINISTRATION

January 8, 2020

MEETING REQUEST DENIED

Alan Dumoff, J.D., M.S.W.
30 Windbrooke Circle
Gaithersburg, MD 20879

Dear Mr. Dumoff

This is in response to your October 30, 2019 letter addressed to Janet Woodcock and Gail Bormel, requesting a meeting to discuss your Citizen Petition received on March 20, 2019 regarding the evaluation of ingredients proposed for functional uses for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Petition) (docket no. FDA-2019-P-1351).

We recognize the value in working with stakeholders to promote the preparation of high quality compounded drug products, and appreciate your interest in engaging with the Agency to facilitate this process. We receive many requests to meet with stakeholders on compounding issues but unfortunately, we generally are unable to conduct individual stakeholder meetings. In addition, our general policy is not to meet with Petitioners and, instead, to rely on the publicly available information contained in the Petition docket. You are free to supplement your Petition at any time or to make additional submissions to the public docket established for the Petition. Accordingly, at this time, we are denying your request for a meeting.

Thank you for contacting us. If you have any questions, please email compounding@fda.hhs.gov for additional information.

Sincerely,

Maria Edisa Gozun -S Digitally signed by Maria Edisa Gozun -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000365626, cn=Maria Edisa Gozun -S
Date: 2020.01.08 11:23:03 -05'00'

Edisa Gozun, Pharm.D.
Director (Acting), Division of Compounded Drugs
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance

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BY FEDERAL EXPRESS

October 30, 2019

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research

Frances Gail Bormel, RPh, JD
Director, Division of Prescription Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Citizens Petition Requesting Evaluation of Ingredients Proposed for Functional Uses for Inclusion on the Bulk Ingredient Compounding List, Revision of FDA Final Rulemaking "List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act" and other relief.
Meeting Request

Dear Drs. Woodcock and Bormel:

On behalf of Petitioners on the above-referenced Citizens Petition, I acknowledge receipt of your September 16, 2019 correspondence and appreciate that the matter is under consideration. We know our Petition presents a number of complex issues and are glad to hear the Agency state that it is involved in an "extensive review and analysis by Agency officials." The FDA has nonetheless remained on a regulatory course noticing removal of a number of clinically significant ingredients from use contrary to the experience of Petitioners and the needs of their patients. The issuance of its second notice of proposed ingredient rulemaking on September 5, 2019 noticing an intention to proceed with the denial of another 26 ingredients (Amendments to the List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act, 84 FR 46688) ("Second Proposed Rule") is based upon the deeply flawed review process described in our Petition.

Especially given that the Agency did not pause in its process nor reflect any consideration in the Second Proposed Rule of the serious issues we have raised, we ask the Agency to meet with us as an opportunity to ensure a fuller understanding on the part of the Agency of the clinical

experience of those with the diverse professional viewpoints we represent, the science behind the functional use of ingredients and the legal requirements we believe the Agency has yet to meet. We hope it would be an opportunity for us as well to better understand the Agency's views and ensure that our professions are responsive in our efforts on the Petition and in practice.

The issues we raise go to the heart of how medicine is researched, its evidence-base developed and practice guidelines developed. Our differences seem to arise more over paradigm than levels of evidence. The narrow criteria and methods adopted by FDA are directly contrary to the systemic models used in personalized, lifestyle, nutritional, functional, integrative and naturopathic medicine. These approaches find evidentiary strength in a full range of sources and methods that fit their approach. Much of medicine, in fact, is principally based on diversified types of evidence we respectfully suggest would not survive the review process applied to compounded drugs.

When we presented at the PCAC meeting about Functional Medicine approaches, a PCAC member seemed to reflect the Agency and PCAC experience generally when she noted that she knew little about functional medicine and wanted to learn more. (Donna Wall, PharmD, PCAC meeting September 12, 2018 p.m. Session at 148-149). Given that many of the nominated ingredients rejected from the positive list are primarily used as part of functional approaches to care, which have been rejected as allowed indications in clear violation of 21 U.S.C. § 321(g)(C), we think a discussion between experienced clinicians and researchers about the nature of clinical decision making and its knowledge base with FDA staff would be constructive.

A large retrospective cohort study just published in JAMA followed outcomes from functional medicine and found significant improvements in HRQoL scores in functional over family health approaches. The authors concluded that "functional medicine may have the ability to improve global health in patients." The article,[1] enclosed, provides some explanation of how functional medicine differs from the disease model FDA has applied to compounded ingredients.

Patients are losing access to valuable therapies now, we consider this to be quite urgent. Please contact me so that we might discuss an agenda focusing on those items that might be fruitful so that we could determine the appropriate subject matter experts to bring to this meeting.

Sincerely,

Alan Dumoff

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[1] Beidelschies M, Alejandro-Rodriguez M, Ji X, et al. Association of the Functional Medicine Model of Care With Patient-Reported Health-Related Quality-of-Life Outcomes. *JAMA Network Open*. 2019;2(10):e1914017. doi:10.1001/jamanetworkopen.2019.14017.

cc: Carol J. Bennet
Deputy Director
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Center for Drug Evaluation and Research

Laura Farr, Executive Director, American Association of Naturopathic Physicians (AANP)

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