Docket ID. FDA-2017-D-6580

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF

NATIONAL HEALTH FREEDOM ACTION

ON THE FDA DRAFT GUIDANCE

Entitled:

Drug Products Labeled as Homeopathic;
Guidance for FDA Staff and Industry
October 2019
Compliance
Revision 1

NHFA – Who we are

National Health Freedom Action (NHFA) is a 501(c)4 non-profit corporation working to promote access to all health care information, services, treatments and products that the people deem beneficial for their own health and survival as well as promoting legislative reform of the laws impacting the right to access and promoting the health of the people of this nation.[1]

NHFA responds to calls year-round from individuals and groups throughout the country that wish to promote legal reform in occupational laws and regulations having to do with health care on the state level, and with federal and international product laws and regulations having to do with access to desired products. NHFA works with citizens to empower them to take action to address these concerns. NHFA educates and trains citizens on health freedom principles and on how to develop and pass proactive health freedom legislation that will ensure the rights of health care practitioners to offer their services and the rights of consumers to have access to products, practitioners, and information.

NHFA staff members draft model legislation, testify at legislative hearings and public policy meetings, and provide strategic support and lobbying assistance and often assist state leaders in developing local health freedom organizations. NHFA is a sister organization to National Health Freedom Coalition, the host for the US Health Freedom Congress, and NHFA participates actively in the Health Freedom Congress and its planning.

Americans Are Aware and Concerned: There is awareness among Americans that personal choice in health care directly impacts how, and whether, a person will gain a full sense of health and wellness. In addition, Americans are deeply concerned about infringements on their ability to make choices caused by regulatory systems that do not adequately protect a person's health care options and personal liberties.

NHFA's Basis for Responding to this revised Draft Guidance

NHFA submitted comments to the original draft guidance on this issue in March of 2018. We are here submitting revised comments given the repeal of Compliance Policy Guide (CPG) 400.400 entitled "*Conditions Under Which Homeopathic Drugs May be Marketed.*" and the production of the new revised draft guidance. NHFA has received multiple correspondences

[1] National Health Freedom Action, www.nationalhealthfreedom.org/nhfa.

from health care practitioners, consumers, and health freedom organizations and leaders across the country requesting an explanation of the revised Draft Guidance and requesting help to protect access to homeopathy. These correspondences reflect mass opposition to any more restrictive laws, regulations, or interpretations of current law that may infringe on full access to homeopathic remedies.

NHFA's legal review of the revised Draft Guidance leads us to continue to oppose the adoption of Guidance and to conclude that the FDA should produce the following:

1. An FDA acknowledgement of the special nature of homeopathic drugs given their high dilution and succussions, in many instances diluted beyond Avogadro's number, and the energetic nature of homeopathic drugs.

2. An endorsement by FDA of the legal status of homeopathic substances as a class, as generally regarded and recognized as safe, and as carrying a presumption of inherent safety in all cases.

Reasoning:

NHFA observes that the current law might lead the FDA to attempt to manage homeopathic drugs with the same process as it manages pharmaceutical drugs. However, that decision would ignore the history of our government's understanding of homeopathic drugs as substances that are unique, highly diluted, generally regarded as safe, and do not pose a public health threat to consumers. Historically, the formal review of homeopathic remedies as pharmaceutical drugs has been set aside given their unique nature. The public is well aware that a pharmaceutical type of enforcement policy for homeopathic remedies is inappropriate. As long as a product is manufactured properly and labeled properly, FDA should have no issue with homeopathic substances being on the market.

NHFA encourages the FDA to consider the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS)[2], homeopathic manufacturers, and the homeopathic practitioner

[2] Website of the Homœopathic Pharmacopœia Convention of the United States (HPCUS), producer of the Homœopathic Pharmacopœia of the United States (HPUS), the official compendium for Homeopathic Drugs in the U.S; accessed online on March 7, 2018, at: http://www.hpus.com.

community as the starting place of authority and guide on homeopathic matters, given their expertise and leadership in the understanding of homeopathic remedies and the entire system of medicine that homeopathic drugs represents. The FDA should uphold the constitutional principle that the least restrictive means of regulation possible should apply in order to honor the rights of consumers to access safe and helpful products. The current proposed guidance does not reflect the actual nature of homeopathic drugs nor the growing demand of consumers of homeopathy for safe alternatives to pharmaceutical drugs. This is disheartening and should be avoided.

Prioritizing enforcement tasks for busy compliance officers is reasonable. However, FDA's list of priorities is misguided. There are already extensive laws and a list of enforcement priorities for unapproved drugs. Additionally, there are clear HPUS Guidelines for Manufacturing Homeopathic Medicines (GMHM) to be followed for homeopathic remedies. Yet, the Draft Guidance proposes to make a new list of priorities for enforcement. Adding new enforcement priorities for homeopathic drugs that go above and beyond those for pharmaceutical drugs is misguided and problematic; especially when doing so without basing them on homeopathic principles and without mentioning the special nature and high dilution and succussion of homeopathic remedies and the existence of special GMHM.

For example, the Draft Guidance states: "*However, the Agency also recognizes that many 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 III below*."[3]. This statement reveals the FDA's focus when it refers to the "agency" and what the "agency" recognizes. This narrow focus is not helpful because it is the manufacturers and the marketers who are the ones who need to recognize which homeopathic drugs will fall outside the categories described. The categories are tailored with broad and vague concepts that are potentially confusing and threatening to manufacturers. For generally regarded as safe products that are manufactured properly and labeled properly, the suggested categories are unhelpful.

Regarding the Categories:

[3] **Drug Products Labeled as Homeopathic:** Guidance for FDA Staff and Industry, Revised Draft October 2019; accessed online December 13, 2019, @ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry

The first three categories and the last category, which have to do with safety, should be merged into one. A single category to cover products not in compliance with HPUS Guidelines for Manufacturing Homeopathic Medicines (GMHM) would be better.

Everyone agrees FDA should carefully monitor whether a product complies with good manufacturing practices and truth in labeling. Yet, when the FDA uses the example of Belladonna and Zinc as substances of intrinsic concern, it fails to lay out the truth about these substances when in the highly diluted homeopathic form. Although Belladonna and Zinc are substances that would not be advisable in significant amounts within a pharmaceutical analysis, it is common knowledge that the extremely high dilution - to the point of insignificance of these substances in the general environment -demonstrates a lack of safety significance. This failure by the FDA to admit and acknowledge these facts and the special nature of the homeopathic form is glaring and reflects ignorance or intentional misrepresentation by the FDA. Homeopathic drugs are generally regarded as safe if properly prepared.

The fourth and fifth categories have to do with? the intended use of a homeopathic remedy and the populations who use the remedies: The FDA does not need enforcement priorities based on use of substances that are generally regarded as safe as long as the manufacturing and labeling is truthful and all disclaimers are present that they are not approved drugs. Consumers have a right and a need to utilize safe homeopathic remedies as they deem fit.

From a manufacturer's point of view the list of compliance priority categories might cause great consternation and confusion, even when GMHM's are followed meticulously, with multiple companies designing multiple interpretations of what is expected of them. **From a consumer point of view**, the enforcement according to these categories is likely to cause suffering and lack of access and appears to be an intentional way, given the broad language used, to allow the FDA to more easily eliminate homeopathic options that are competing in the marketplace with pharmaceutical drugs for non-compliance reasons.

The FDA has historically been forthright in recognizing homeopathic drugs as having a special nature and the need for treatment differently from that of pharmaceutical drugs. This should continue.

For example, in 1972, in the Federal Register when discussing new drugs and "Procedures for Classification of Over-the-Counter Drugs", the following treatment of homeopathic remedies was noted:

> *"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."*[4]

And, in 1988, the FDA specifically addressed homeopathy again giving guidance in the Compliance Policy Guidance 400.400 on homeopathy, in part, as follows:

> *"The Federal Food, Drug, and Cosmetic Act (the Act) recognizes as official the drugs and standards in the Homeopathic Pharmacopeia of the United States and its supplements (Sections 201 (g)(1) and 501 (b), respectively). Until recently, homeopathic drugs have been marketed on a limited scale by a few manufacturers who have been in business for many years and have predominantly served the needs of a limited number of licensed practitioners. In conjunction with this, homeopathic drug products historically have borne little or no labeling for the consumer.*
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> *Today the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products. Those products that are offered for treatment of serious disease conditions, must be dispensed under the care of a licensed practitioner. Other products, offered for use in self-limiting conditions recognizable by consumers, may be marketed OTC.*
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> *This document provides guidance on the regulation of OTC and prescription homeopathic drugs and delineates those conditions under which homeopathic drugs may ordinarily be marketed in the U.S....).*[5]

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[4] Quote from: Draft Guidance, Drug Products Labeled as Homeopathic; Guidance for FDA Staff and Industry; accessed online March 7, 2018 at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm589373.pdf, and link to the 1972 Federal Register archive of 37 FR 9464, 9466 (May 11, 1972) accessed online March 7, 2018 at: https://www.gpo.gov/fdsys/pkg/FR-1972-05-11/pdf/FR-1972-05-11.pdf

[5] Compliance Policy Guide, Sec. 400.400, Conditions Under Which Homeopathic Drugs May be Marketed, accessed online March 7, 2018, at: https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm

The new 2019 Draft Guidance acknowledges the special 1972 status: "*FDA makes GRAS/E determinations for OTC drugs marketed under the OTC Drug Review. FDA has not reviewed any homeopathic drug products under the OTC Drug Review, because the Agency categorized these products as a separate category and deferred consideration of them*."[6] (37 FR 9464, 9466 (May 11, 1972)).

The FDA, picking up where it left off in 1972 or 1988, could have come to an official conclusion that homeopathic drugs as a class are GRAS/E, generally recognized as safe, as it has done for so many other OTC substances on the market. **Instead the FDA** is here recommending treating all homeopathic drugs as toxic pharmaceutical substances that legally require a "new drug" application; *"Accordingly, absent a determination that a homeopathic drug product is not a "new drug" under section 201(p), all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act. There are currently no homeopathic drug products that are approved by FDA*".[7] FDA is literally recommending that even though all homeopathic drugs are illegally being marketed without new drug approval, they will turn their heads and ignore many of the supposed transgressions based upon their priority of prosecutions. Guilty until proven innocent.

The chilling effect of this type of regulatory approach is unconscionable and a blatant disregard for the truth.

Summary

NHFA's concern is that the Draft Guidance does not acknowledge the special nature and safety of homeopathic drug products and does not offer a helpful solution to manufacturers

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[6] **Drug Products Labeled as Homeopathic:** Guidance for FDA Staff and Industry, Revised Draft October 2019; accessed online December 13, 2019, @ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry

[7] **Drug Products Labeled as Homeopathic:** Guidance for FDA Staff and Industry, Revised Draft October 2019; accessed online December 13, 2019, @ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry

and marketers of homeopathic drugs. The Guidance moves homeopathic drugs into a general pharmaceutical drug regulation system without the protections homeopathic drug products deserve given their special nature.

NHFA respectfully requests that:

1. The FDA acknowledge the special nature of homeopathic drugs given their high dilution and succussions, and the energetic nature of homeopathic drugs.

2. FDA declare that homeopathic drugs are exempt from being classified as "new drugs" and from all related premarket approval requirements and that homeopathic drugs as a class have a sufficient degree of dilution and historical record of safety, have a presumption of safety, and are generally recognized as safe (GRAS).

Thank you for your consideration.

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