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ON THE FDA DRAFT GUIDANCE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

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NHFA's Basis for Responding to the Draft Guidance

NHFA has received multiple correspondences from health care practitioners, consumers, and health freedom organizations and leaders across the country requesting an explanation of the Draft Guidance and help to protect access to homeopathy.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.

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

NHFA's legal review of the Draft Guidance leads us to oppose the Draft Guidance and to conclude that it should be withdrawn in its entirety or be amended to ensure clear regulatory guidance for the homeopathic industry and protection of access by consumers. Given NHFA's leadership role in protecting the personal liberty rights of health care consumers, NHFA is providing the following comments.

Reasoning:

NHFA holds that, given the detailed guidance that FDA already provides for homeopathic manufacturers under the current Compliance Policy Guide, Sec. 400.400, Conditions Under Which Homeopathic Drugs May be Marketed[2], the laws and regulations specific to Unapproved Over -the-Counter Drugs[3], and the remarkable work of the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS)[4] including their provision of expert leadership in the understanding of homeopathic remedies, this new guidance and interpretation of existing federal law is unhelpful and unnecessary. In fact, the lack of specific guidance in the new proposed Draft Guidance document has potential for causing mass confusion and discouragement of the production of homeopathic remedies, attributable to fear of non-compliance.

Prioritizing enforcement tasks for busy compliance officers is reasonable. But that is not all that is proposed in the Draft Guidance. There are already extensive laws and a list of

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[2] 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

[3] Guidance for FDA Staff and Industry, Marketed Unapproved Drugs – Compliance Policy Guide, accessed online March 7, 2018 at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm070290.pdf

[4] 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.

enforcement priorities for unapproved drugs. There is already a guidance document specifically for homeopathic remedies. Yet, the Draft Guidance proposes to make a new list of priorities for enforcement different than the current list of enforcement priorities for unapproved drugs and to remove CPG 400.400 which has provided very clear and specific policy guidelines for homeopathic manufacturers and marketers for decades. Adding new enforcement priorities for homeopathic drugs above and beyond those of pharmaceutical drugs, without mentioning the special nature of homeopathic remedies themselves in the document, is discriminatory and will create confusion. Replacing the CPG 400.400 specific guidelines with vague and broadly worded "risk-based approach" to compliance issues without providing positive affirmative actions that will not be challenged, leaves much to the imagination and legal discernment. From a manufacturer's point of view the list of compliance issues might cause great consternation and confusion, with multiple companies designing multiple interpretations of what is expected of them. From a consumer point of view, it is likely to appear to be an intentional way with broad language to allow the FDA to more easily eliminate homeopathic options for non-compliance reasons.

For example, when the Draft Guidance states "However, *the Agency also recognizes that many products labeled as homeopathic will fall outside the risk-based categories described below*"[5], it does not offer any specifics as to which products those might be. We would ask: "Would those be the products complying with the old CPG 400.400?" And, if so, then: "Why not state that fact and append those specific guidelines to the draft?"

Although homeopathic remedies are by law included in the statutory definition of drug, and homeopathic remedies are unapproved drugs under the FDA, the FDA has historically been forthright in recognizing their special nature and the need for treatment different from that for pharmaceutical drugs.

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

[5] 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

> *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."*[6]

It is now 46 years later and the FDA has not completed the OTC drug review and homeopathic remedies have not been reviewed.

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.*
>
> *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.*
>
> *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. Agency compliance personnel should particularly*

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[6] 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

> *consider whether a homeopathic drug is being offered for use (or promoted) significantly beyond recognized or customary practice of homeopathy. If so, priorities and procedures concerning the agency's policy on health fraud would apply. (See CPG 7150.10 "Health Fraud-Factors in Considering Regulatory Action" 6/5/87).*[7]

The new Draft Guidance acknowledges the special 1972 status, that the FDA "has not reviewed any drug products labeled as homeopathic under the OTC Drug Review, because the Agency categorized these products as a separate category and deferred consideration of them. (37 FR 9464, 9466 (May 11, 1972))."

And the new draft guidance acknowledges the existence of the special 1988 CPG 400.400 guidance document that gives special guidelines for the marketing of homeopathic drugs.

But it gives no rationale as to:

1. Why CPG 400.400 is being eliminated other than FDA has determined that *"It is in the best interest of public health to issue a new guidance that applies a risk-based enforcement approach to drug products labeled as homeopathic and marketed without the required FDA approval, consistent with FDA's risk-based regulatory approaches generally."*[8]; and

2. Why the current enforcement priorities for unapproved drugs listed in the Guidance document entitled "*Marketed Unapproved Drugs – Compliance Policy Guide"* should be different than the enforcement priorities recommended for homeopathic drugs?

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[7] 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

[8] 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

The value of CPG 400.400

The value of the CPG 400.400 is that it is a proactive and affirmative document that can be easily continued or even amended if needed because it addresses and acknowledges the special nature of homeopathic remedies as opposed to the general treatment of drugs.

For example:

1. CPG 400.400 begins with a definition of homeopathy and lays out the principles of the law of similars and dilution methods. It even notes a definition of a "proving"; "[a] proving is synonymous with the homeopathic procedure (identified in HPUS as a "Research Procedure") which is employed in healthy individuals to determine the dose of a drug sufficient to produce symptoms."[9]

2. The CPG 400.400 gives specific proactive guidance for OTCs regarding: Principal Display Panel; Statement of Identity; Declaration of Net Quantity of Contents; Indications for Use; Directions for Use; and Warnings.[10] In a number of these categories the CPG 400.400 refers to existing Code of Federal Regulations that must be complied with.

3. CPG 400.400 gives clear statements about use such as *"Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products."*[11]

4. CPG 400.400 acknowledges the existence of Home Remedy Kits and understands that these vials can be very small. FDA makes a clear statement that: "*Home Remedy Kits may contain several products used for a wide range of conditions amenable to OTC use. When limited space does not allow for a list of those conditions on the labels of the products, the required labeling must appear in a pamphlet or similar informational piece which is enclosed in the kits. However, as a minimum, each product must also bear a label containing a statement of identity and potency."*[12]

[9] Compliance Policy Guide, Sec. 400.400. Id.
[10] Id.
[11] Id.
[12] Id.

4. CPG 400.400 literally acknowledges the unique nature of homeopathic remedies in their compliance issues with Good Manufacturing Guidelines when it states:

> *"However, due to the unique nature of these drug products, some requirements of 21 CFR 211 (GMP) are not applicable, as follows:*
>
> *1. Section 211.137 (Expiration dating) specifically exempts homeopathic drug products from expiration dating requirements.*
>
> *2. Section 211.165 (Testing and release for distribution): In the Federal Register of April 1, 1983 (48 FR 14003), the Agency proposed to amend 21 CFR 211.165 to exempt homeopathic drug products from the requirement for laboratory determination of identity and strength of each active ingredient prior to release for distribution.*
>
> *Pending a final rule on this exemption, this testing requirement will not be enforced for homeopathic drug products."*[13]

The questions from the public now are:

Why is CPG 400.400 being completely repealed and not being allowed to stand along-side and in conjunction with the risk-based approach?

Is there something in CPG 400.400 that is allowing something that the risk-based approach might want to dis-allow? If so, what are those items and how can we address them directly before chaos and confusion ensues.

Concerns about enforcement priorities for homeopathic drugs

The Draft Guidance has created a list of enforcement priorities for homeopathic drugs above and beyond the current enforcement priorities for all unapproved over the counter drugs listed in the Guidance Document for Marketed Unapproved Drugs – Compliance Policy Guide.[14]

[13] Id.
[14] Guidance for FDA Staff and Industry, Marketed Unapproved Drugs – Compliance Policy Guide, accessed online March 7, 2018 at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm

The following is a table showing the enforcement priorities for unapproved drugs in the current Guidance Document for Marketed Unapproved Drugs – Compliance Policy Guide compared to the enforcement priorities of the proposed Draft Guidance for Drug Products Labeled as Homeopathic enforcement priorities and contains an additional column for NHFA's comments.

Current Guidance Document for Marketed Unapproved Drugs – Compliance Policy Guide[15]	**Draft Guidance for Drug Products Labeled as Homeopathic**[16]	**NHFA Comments**
Enforcement Priorities Consistent with our risk-based approach to the regulation of pharmaceuticals, FDA intends to continue its current policy of giving higher priority to enforcement actions involving unapproved drug products in the following categories:	***Enforcement and Regulatory Priorities*** In developing a risk-based approach, FDA has identified certain categories of drug products labeled as homeopathic and marketed without the required FDA approval as potentially posing higher risks to public health. FDA intends to prioritize	***Both pharmaceutical drugs and homeopathic drugs have drugs in the "unapproved drug" category.*** If the FDA plans to have different treatment of these two categories, it must lay out the foundation forth those differences. For

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[15] Id.

[16] 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

	enforcement and regulatory actions involving drug products labeled as homeopathic and marketed without the required FDA approval in the following categories:	example, the language set for in the CPG 400.400.
Drugs with potential safety risks. Removing potentially unsafe drugs protects the public from direct and indirect health threats.	***Products with reported safety concerns***. For example, MedWatch reports or other information submitted to the Agency can indicate or signal a potential association between the product and an adverse event, medication errors, or other safety issues.	***No Comment***
	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 U.S.C. 147 812;	***There is no corresponding enforcement priority listed in the Marketed Unapproved Drugs – Compliance Policy Guide.*** The examples given do not explain that a highly diluted substance containing even less than a typical environmental exposure to a substance that would normally present a potentially significant safety concern in daily life, might not in

	►Multiple ingredients that, when used in combination, raise safety concerns due to possible interactions, synergistic effects, or additive effects of the various ingredients; and, ►Ingredients that pose potential toxic effects, particularly when those ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are not adequately controlled in the manufacturing process.	fact be a priority for enforcement. This section should comment on ingredients that rise to the level of a dilution ratio that could cause harm to a human when exposed to more than the accepted daily exposure.
	Products for routes of administration other than oral and topical. For example, unapproved injectable drug products and unapproved ophthalmic drug products pose a greater risk of harm to users due to their routes of administration (e.g., bypassing some of the body's natural defenses, differences in absorption) and the potential risk of harm from contamination.	***There is no corresponding enforcement priority listed in the Marketed Unapproved Drugs – Compliance Policy Guide*** In this case, the pharmaceutical substances would be more of a risk generally. The Draft Guidance should comment here on the fact that an unapproved injectable or ophthalmic product that consists of such a highly diluted substance that the ingredient concentration is lower than what the

		concentration would be that might negatively impact the human body, would not be an enforcement priority.
	Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases and conditions. Unapproved products for serious and/or life-threatening diseases and 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 NDA or BLA approval processes.	***There is no corresponding enforcement priority listed in the Marketed Unapproved Drugs – Compliance Policy Guide.*** However, many unapproved pharmaceuticals and? over the counter drugs are marketed to impact serious diseases. The CPG 400.400 deals with this issue clearly when it states: "Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products."

	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 their varying ability 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.	***There is no corresponding enforcement priority listed in the Marketed Unapproved Drugs – Compliance Policy Guide.*** However, the Code of Federal Regulations for Unapproved Drugs spells out the requirements for labeling and warnings to consumers. In terms of actual potential for harm to vulnerable populations, it is common knowledge that a highly diluted substance without the actual substance in it or at very high levels of dilution would be less harmful to populations than a pharmaceutical substance. In addition, the freedom to utilize whatever medical treatment a person wishes is a fundamental right in our country. The FDA's responsibility to protect populations from fraudulent products is expected for all populations.
Drugs that lack evidence of effectiveness.		***There is no corresponding enforcement priority***

Removing ineffective drugs protects the public from using these products in lieu of effective treatments. Depending on the indication, some ineffective products would, of course, pose safety risks as well.		***listed in the Draft Guidance for Drug Products Labeled as Homeopathic*** It would have been helpful in the Draft Guidance to spell out the essence of homeopathy and the way that provings are done, and the expectations of a homeopathic drug in terms of effectiveness or impact on the human body, mind, and spirit. CPG 400.400 does a good beginning of this understanding.
Health fraud drugs. FDA defines health fraud as "[t]he deceptive promotion, advertisement, distribution or sale of articles . . . that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientific ally proven safe and effective for such purposes. Such practices may be deliberate or done without adequate knowledge or understanding of the article" (CPG Sec. 120.500). Of	***Products deemed adulterated under section 501 of the FD&C Act***. For example, if a product purports to be or is represented as a product recognized in an official compendium but its strength, quality, or purity differs from the standards set forth in that official compendium (defined by 21 U.S.C. 321 as the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any	***No Comment***

highest priority in this area are drugs that present a direct risk to health. Indirect health hazards exist if, as a result of reliance on the product, the consumer is likely to delay or discontinue appropriate medical treatment. Indirect health hazards will be evaluated for enforcement action based on section 120.500, Health Fraud - Factors in Considering Regulatory Action (CPG Sec. 120.500). FDA's health fraud CPG outlines priorities for evaluating regulatory actions against indirect health hazard products, such as whether the therapeutic claims are significant, whether there are any scientific data to support the safety and effectiveness of the product, and the degree of vulnerability of the prospective user group (CPG Sec. 120.500).	supplement to any of them), or if there are significant violations of current good manufacturing practice requirements.	
Drugs that present direct challenges to the new drug approval and OTC drug monograph systems. The drug approval and OTC drug monograph systems are designed to avoid the risks		***No Comment***

associated with potentially unsafe, ineffective, and fraudulent drugs. The drugs described in the preceding three categories present direct challenges to these systems, as do unapproved drugs that directly compete with an approved drug, such as when a company obtains approval of a new drug application (NDA) for a product that other companies are marketing without approval (see section III.C, Special Circumstances – Newly Approved Product). Also included are drugs marketed in violation of a final and effective OTC drug monograph. Targeting drugs that challenge the drug approval or OTC drug monograph systems buttresses the integrity of these systems and makes it more likely that firms will comply with the new drug approval and monograph requirements, which benefits the public health.		
Unapproved new drugs that are also violative of the Act in other ways. The Agency also intends, in		***No Comment***

circumstances that it considers appropriate, to continue its policy of enforcing the preapproval requirements of the FD&C Act against a drug or firm that also violates another provision of the FD&C Act, even if there are other unapproved versions of the drug made by other firms on the market. For instance, if a firm that sells an unapproved new drug also violates current good manufacturing practice (CGMP) regulations, the Agency is not inclined to limit an enforcement action in that instance to the CGMP violations. Rather, the Agency may initiate a regulatory action that targets both the CGMP violation and the violation of section 505 of the FD&C Act (21 U.S.C. 355). This policy efficiently preserves scarce Agency resources by allowing the Agency to pursue all applicable charges against a drug and/or a firm and avoiding duplicative action. See United States v. Sage Pharmaceuticals, Inc., 210 F.3d 475, 479-80 (5th		

Cir. 2000).		
Drugs that are reformulated to evade an FDA enforcement action. The Agency is also aware of instances in which companies that anticipate an FDA enforcement action against a specific type or formulation of an unapproved product have made formulation changes to evade that action but have not brought the product into compliance with the law. Companies should be aware that the Agency is not inclined to exercise its enforcement discretion with regard to such products. Factors that the Agency may consider in determining whether to bring action against the reformulated products include, but are not limited to, the timing of the change, the addition of an ingredient without adequate scientific justification (see, for example, 21 CFR 300.50 and 330.10(a)(4)(iv)), the creation of a new combination that has not previously been marketed, and the claims made for the new product.		***No Comment***

Summary

NHFA's concern is that the Draft Guidance is eliminating language that acknowledges the special nature of homeopathic remedies and dilutions and moves them into the general drug language without acknowledgement of special understanding or treatment. On the one hand the Draft Guidance states, "*Drugs marketed without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling*" and "*continued marketing of products that have neither been approved by FDA nor found to be GRAS/E is a public health concern*"[17], yet, on the other hand, the Draft Guidance is eliminating the most direct and clear document of guidance provided to the homeopathic community, manufacturers, and marketers; a document that promotes safety and public awareness; a document that attempts to spell out the special nature of homeopathic remedies and acknowledge their general safety. In addition, it is adding new enforcement priorities without acknowledging the special nature of homeopathic drugs, dilutions, provings, and a host of principles that contribute to their generally regarded as safe nature.

NHFA reviewed the risk-based categories already in the Code of Federal Regulations and acknowledges them and assumes that these categories have been historically used for years with drug enforcement actions of all kinds, including homeopathic remedies. However, in the new enforcement priorities there is no acknowledgement of taking into consideration the special nature of homeopathic dilutions in enforcement actions and the absence of life-threatening amounts of ingredients. It is common knowledge that these highly diluted substances are generally safe yet, by eliminating CPG 400.400 and by adding new homeopathic drug specific enforcement priorities above and beyond current unapproved drug enforcement priorities, FDA is framing these drug substances into a general drug category similar to pharmaceutical drugs.

[17] 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

NHFA respectfully requests that:

1. The deletion of CPG 400.400 be eliminated from the Draft Guidance and that CPG 400.400 be returned it to its rightful place in the homeopathic community;

and

2. The enforcement priorities that go above and beyond the enforcement priorities currently in place for unapproved drugs be eliminated from the Draft Guidance.

Thank you for your consideration.

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