



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6580]

Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for FDA staff and industry entitled “Drug Products Labeled as Homeopathic.” This draft guidance describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-6580 for "Drug Products Labeled as Homeopathic." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301-796-3600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA staff and industry entitled “Drug Products Labeled as Homeopathic.” This draft guidance describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval. Simultaneous with the issuance of the final guidance, FDA will withdraw Compliance Policy Guide (CPG) 400.400, “Conditions Under Which Homeopathic Drugs May be Marketed”, issued on May 31, 1988.

Homeopathy is an alternative medical practice that has an historical basis in theory and practice first systematized in the late 1700s. Homeopathy is generally based on two main principles: (1) a substance that causes symptoms in a healthy person can be used in diluted form to treat symptoms and illnesses (known as “like-cures-like”) and (2) the more diluted the substance, the more potent it is (known as the “law of infinitesimals”).

The definition of “drug” in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g)(1)) includes articles recognized in the Homeopathic Pharmacopoeia of the United States (HPUS) or any supplement to it. As such, homeopathic drugs are subject to the same regulatory requirements as other drugs. Generally, a drug, including a homeopathic drug, is considered a “new drug” if it is not generally recognized by qualified experts as safe and effective (GRAS/E) for its labeled uses (section 201(p) of the FD&C Act). FDA makes GRAS/E determinations for over-the-counter (OTC) drugs marketed under the OTC Drug Review (see 21 CFR part 330). 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 at 9466 (May 11, 1972)). Under section 505(a) of the FD&C Act (21 U.S.C. 355(a)), before any “new drug” is marketed, it must be the subject of an approved application submitted pursuant to section 505(b) or section 505(j) of the FD&C Act; however, a biological product with an approved license under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) is not required to have an approved application under section 505 of the FD&C Act. Accordingly, absent a determination that a drug product labeled as homeopathic is not a “new drug” under section 201(p), all drug products labeled as homeopathic are subject to the premarket approval

requirements in section 505 of the FD&C Act or section 351 of the PHS Act. There are no drug products labeled as homeopathic that are approved by FDA.

In May 1988, FDA's Center for Drug Evaluation and Research issued CPG 400.400 entitled "Conditions Under Which Homeopathic Drugs May be Marketed." As stated in the 1988 CPG, it delineates the conditions, including conditions related to ingredients, labeling, prescription status, and current good manufacturing practice, under which homeopathic drug products may ordinarily be marketed.

In light of the growth of the industry and passage of more than 2 decades since the 1988 CPG's issuance, FDA announced on March 27, 2015, that it was evaluating its regulatory framework for these products. In April 2015, FDA held a public hearing to obtain information and comments from stakeholders about the current use of drug products labeled as homeopathic, as well as the Agency's regulatory framework for such products (Docket No. FDA-2015-N-0540; available at <https://www.regulations.gov/docket?D=FDA-2015-N-0540>). FDA sought broad public input on its enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health.

As a result of the Agency's evaluation, including consideration of the public input received on this issue, 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 in the United States without the required FDA approval, consistent with FDA's risk-based regulatory approaches generally. The Agency generally intends to apply a risk-based enforcement approach to the manufacturing, distribution, and marketing of drug products labeled as homeopathic, as described in the draft guidance, when finalized. However,

the Agency has limited enforcement resources and recognizes that many such products likely will fall outside the risk-based categories described in the draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on drug products labeled as homeopathic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: December 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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