

Generally, a drug, including a homeopathic drug, is considered a “new drug” if it is not generally recognized as safe and effective by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling (section 201(p) of the FD&C Act). CPG 400.400 did not, and legally could not, provide a path for legal marketing of unapproved new drugs, including those that are homeopathic. Rather, the CPG merely described an enforcement policy regarding homeopathic drug products. The Agency does not have authority to exempt a product or class of products that are new drugs under the FD&C Act from the new drug approval requirements of the FD&C Act. (See *Cutler v. Kennedy*, 475 F. Supp. 838, 856 (D.D.C. 1979); *Hoffman-LaRoche v. Weinberger*, 425 F. Supp. 890, 892–894 (D.D.C. 1975). See also *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 327 (2014) (“An agency confronting resource constraints may change its own conduct, but it cannot change the law.”)).

The Agency’s interest in its general risk-based enforcement approach also justifies withdrawing an outdated policy that does not reflect that approach. Additionally, withdrawal of the CPG is appropriate given the recent growth of safety concerns associated with homeopathic drug products—including concerns regarding products associated with serious adverse events and otherwise presenting significant safety risks and serious violations of CGMP requirements—and the increasing number of consumer exposures due to the continued expansion of the homeopathic industry since issuance of the CPG.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23334 Filed 10–24–19; 8:45 am]

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Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry

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announcing the availability of a revised draft guidance for FDA staff and industry entitled “Drug Products Labeled as Homeopathic.” The revised draft guidance, like the original version, describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological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 that potentially pose higher risk to public health. In response to comments received, we have revised the draft guidance and are reissuing it in draft form to enable the public to review and comment before it is finalized.

DATES: Submit either electronic or written comments on the draft guidance by January 23, 2020 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.

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 (CBER), 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

In the **Federal Register** on December 20, 2017 (82 FR 60403), FDA announced the availability of a draft guidance for FDA staff and industry entitled “Drug Products Labeled as Homeopathic.” This draft guidance was intended to describe 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 that potentially pose higher risk to public health.

In response to comments received, we have revised the draft guidance and are reissuing it to enable the public to review and comment before it is finalized. In particular, we have added a definition of “homeopathic drug product” for purposes of the guidance, added additional explanation of some of the safety issues that contributed to the development of the draft guidance, and clarified the intent to use risk-based factors to prioritize enforcement and regulatory actions involving homeopathic products that are marketed without required FDA approval. In addition, the revised draft guidance removes the statement that the Agency will withdraw the compliance policy guide (CPG) simultaneous with the issuance of the final guidance. Elsewhere in this **Federal Register**, FDA is announcing the withdrawal of CPG 400.400.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR

10.115). The revised 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.

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> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0847. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

Understanding patients, consumers, and healthcare professionals’ perceptions and behaviors plays an important role in improving FDA’s regulatory decisionmaking processes and communications impacting various stakeholders. The methods used to achieve these goals include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and focus group interviews. The methods used serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative and quantitative research tool, and have two major purposes:

1. To obtain information that is useful for developing variables and measures for formulating the basic objectives of social and behavioral research and
2. To assess the potential effectiveness of FDA communications, behavioral interventions and other materials in reaching and successfully communicating and addressing behavioral change with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop communication and behavioral strategies research, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA’s Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or