



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2015-N-0540]

Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to obtain information and comments from stakeholders about the current use of human drug and biological products labeled as homeopathic, as well as the Agency's regulatory framework for such products. These products include prescription drugs and biological products labeled as homeopathic and over-the-counter (OTC) drugs labeled as homeopathic. FDA is seeking participants for the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, and industry. FDA is seeking input on a number of specific questions, but is interested in any other pertinent information participants would like to share.

DATES: The public hearing will be held on April 20 and 21, 2015, from 9 a.m. to 4 p.m. The meeting may be extended or may end early depending on the level of public participation.

Register to attend or provide oral testimony at the hearing by April 13, 2015. See

REGISTRATION AND REQUEST TO PROVIDE ORAL TESTIMONY for information on how to register or make an oral presentation at the hearing. Written or electronic comments will be accepted until June 22, 2015.

ADDRESS: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503A, Silver Spring, MD, 20993-0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Lesley DeRenzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 240-402-4612, FAX: 301-847-8747, Lesley.derenzo@fda.hhs.gov; or Cynthia Ng, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-7512, FAX: 301-847-8747, cynthia.ng@fda.hhs.gov.

REGISTRATION AND REQUEST TO PROVIDE ORAL TESTIMONY: The public hearing is free and seating will be on a first-come, first-served basis. If you wish to attend or make an oral presentation, see section III (Attendance and/or Participation in the Public Hearing) for information on how to register and the deadline for registration. If you cannot attend in person, information about how you can access a live Webcast will be located at <https://collaboration.fda.gov/hprapril2015/>.

COMMENTS AND TRANSCRIPTS: You may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852. You should annotate and organize your comments to identify the specific questions or topic to which they refer. It is only necessary to send one set of comments. Please identify your comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts of the hearing will be available for review at the Division of Dockets Management and at <http://www.regulations.gov> approximately 45 days after the hearing. You may submit a request to obtain a hard copy or CD-ROM transcript. Send your request to the Division of Freedom of Information (ELEM-1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

FDA is evaluating its current enforcement policies for drug products labeled as homeopathic from scientific, risk, and process perspectives. The Agency is now soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last approximately 25 years.

I. Background

A. Homeopathic Products and the Federal Food, Drug, and Cosmetic Act

The definition of a “drug” under the Federal Food, Drug, and Cosmetic Act (FD&C Act) includes: (1) Articles recognized in the official United States Pharmacopoeia (USP), official Homoeopathic Pharmacopoeia of the United States (HPUS); (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or

other animals. See section 201(g)(1)(A) to (C) of the FD&C Act (21 U.S.C. 321(g)(1)(A) to(C)). Accordingly, an article that meets this definition of a “drug” is subject to regulation under the FD&C Act, regardless of whether it is labeled as homeopathic. An article that also meets the definition of a “biological product” (as defined in section 351(i) of the Public Health Service Act (PHS Act) (42 U.S.C 262(i))) is subject to regulation under both the FD&C Act and the PHS Act.

The FD&C Act recognizes the HPUS, along with the USP, as an official compendium. See section 201(j) of the FD&C Act. The HPUS is produced by a non-governmental organization known as the Homeopathic Pharmacopœia Convention of the United States (HPCUS) and has been in continuous publication since 1897 (Ref. 1). The HPCUS determines which ingredients, including permissible potency levels, are officially monographed homeopathic ingredients. To date, there are over 1200 officially monographed ingredients in the HPUS. Since 2004, the HPCUS has added over 500 new ingredient monographs. The standards set forth in the HPUS and the USP affect the naming, quality, and labeling of drug products. See e.g., sections 501(b) and 502(g) of the FD&C Act (21 U.S.C. 351(b) and 352(g)).

Nothing in the FD&C Act exempts drugs labeled as homeopathic from any of the requirements related to approval, adulteration, and misbranding, including labeling requirements. If a drug labeled as homeopathic is a new drug under the FD&C Act, it is subject to the same premarket approval requirements and the same standards for safety and efficacy as all new drugs. A new drug is defined, in part, as any drug that is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof. See section 201(p) of the FD&C Act).

B. Homeopathic Drugs and the OTC Drug Review

In 1972, FDA initiated rulemaking procedures (the OTC Drug Review) to determine which OTC drugs are generally recognized among qualified experts as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use. See “Procedures for Classification of Over-the-Counter Drugs” (37 FR 9464, May 11, 1972). FDA deferred review of drugs labeled as homeopathic due to the uniqueness of homeopathic medicine and stated that FDA would review them as a separate category at a later time (37 FR 9464 at 9466). To date, FDA has not reviewed this class of products for safety and efficacy. Accordingly, there are currently no FDA monographs for drug products labeled as homeopathic.

C. FDA’s Compliance Policy Guide

Since 1988, prescription and nonprescription drug products labeled as homeopathic have been manufactured and distributed without FDA approval under the enforcement policies set forth in FDA’s Compliance Policy Guide (CPG) 400.400 entitled “Conditions Under Which Homeopathic Drugs May be Marketed” (see 53 FR 21728, June 9, 1988). The CPG defines a homeopathic drug as any drug labeled as being homeopathic which is listed in the HPUS, an addendum to it, or its supplements. The CPG includes conditions specific to ingredients, labeling, prescription status, and current good manufacturing practice. The CPG can be found at <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm>.

D. Growth in the Sale of Drugs Labeled as “Homeopathic”

The homeopathic drug industry has continued on an upward growth trajectory since FDA issued its CPG in 1988, especially with respect to OTC drug products labeled as homeopathic. The CPG noted that, at the time of original publication in 1988, the homeopathic drug market

was a multimillion dollar industry in the United States. In 2007, the National Health Interview Survey, conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, estimated that adults spent about \$2.9 billion on the purchase of homeopathic medicine (Ref. 2). Many drugs labeled as homeopathic are sold OTC in major retail stores and are often marketed as natural, safe, and effective alternatives to other prescription and nonprescription products.

E. Safety of Drug Products Labeled as Homeopathic

Drugs products labeled as homeopathic can contain a wide range of substances, including ingredients derived from plants, healthy or diseased animal or human sources, minerals, and chemicals (either as active or inactive ingredients). As with ingredients in other drug and biological products, homeopathic ingredients, even if highly diluted, can cause side effects, drug interactions, and allergic or other adverse reactions. Negative health effects from drug products labeled as homeopathic have been reported through the FDA's Adverse Event Reporting System and the National Poison Data System (NPDS), which is maintained by the American Association of Poison Control Centers and tracks human poison exposure cases. Data in the NPDS pertaining to homeopathic drug products is tracked under the category "Homeopathic Agents." The 2012 American Association of Poison Control Center Annual Report indicated that there were 10,311 reported poison exposure cases related to "Homeopathic Agents," with 8,788 of those reported cases attributed to children 5 years of age and younger (Ref. 3). Of the 10,311 reported cases, 697 required treatment in a health care facility (Id.).

II. Scope of the Public Hearing

FDA is seeking broad public input on the current enforcement policies related to drug products labeled as homeopathic in an effort to better promote and protect the public health.

FDA has developed a list of questions to facilitate a more productive discussion at the public hearing. This list is not intended to be exclusive, and FDA encourages comments on other matters related to the development and regulation of drug and biological products labeled as homeopathic. Issues that are of specific interest to the Agency include the following:

- What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?
- What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic?
- Are the current enforcement policies under the CPG appropriate to protect and promote public health in light of the tremendous growth in the homeopathic drug market? Are there alternatives to the current enforcement policies of the CPG that would inform FDA's regulatory oversight of drugs labeled as homeopathic? If so, please explain.
- Are there areas of the current CPG that could benefit from additional clarity? If so, please explain.
- Is there information regarding the regulation of homeopathic products in other countries that could inform FDA's thinking in this area?
- A large majority of human drug products labeled as homeopathic are marketed as OTC drugs. These products are available for a wide variety of indications, and many of these indications have never been considered for OTC use under a formal regulatory process. What would be an appropriate regulatory process for evaluating such indications for OTC use?
- Given the wide range of indications on drug products labeled as homeopathic and available OTC, what processes do companies currently use to evaluate whether such

products, including their indications for use, are appropriate for marketing as an OTC drug?

- Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic? If not, what information, including, for example, information in labeling, would allow consumers and health care providers to be better informed about products labeled as homeopathic?

III. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. If you wish to make an oral presentation during the hearing, you must register by submitting either an electronic or a written request by 5 p.m. on April 13, 2015, to Lesley DeRenzo or Cynthia Ng (see FOR FURTHER INFORMATION CONTACT). Submit electronic requests to CDERHOMEOPATHICPRODUCT@fda.hhs.gov. You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization, etc.). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. FDA encourages individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Registrants will receive confirmation once they have been accepted to attend the meeting. FDA may limit both the number of participants from individual organizations and the total number of attendees based on space limitations. Registered presenters should check in before the hearing.

Participants should submit a copy of each presentation to Lesley DeRenzo or Cynthia Ng (see FOR FURTHER INFORMATION CONTACT) no later than 5 p.m. on April 13, 2015. We will file the hearing schedule, indicating the order and time allotted for each presenter, with the

Division of Dockets Management (see COMMENTS AND TRANSCRIPTS). FDA will post an agenda of the public hearing and other background material at least 3 days before the public hearing, along with additional information, at:

<http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm> (select this hearing from the events list).

We will mail, email, or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

If you need special accommodations due to a disability, contact Lesley DeRenzo or Cynthia Ng (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the hearing.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). A presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the relevant centers, will conduct the hearing.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (§ 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be

transcribed as stipulated in § 15.30(b). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. The Homeopathic Pharmacopoeia of the United States (HPUS), “What is the HPUS?”, available at <http://www.hpus.com/what-is-the-hpus.php> (last visited Dec. 23, 2014).
2. Nahin, R. L., P. M. Barnes, B. J. Stussman, and B. Bloom, “Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007.” National Health Statistics Reports; no 18. Hyattsville, MD: National Center for Health Statistics, 2009.
3. James B. Mowry, et al., “2012 Annual Report of the American Association of Poison Control Centers’ National Poison Data System (NPDS): 30th Annual Report,” 51 Clinical Toxicology, 949, 1188 (2013).

Dated: March 20, 2015.

Leslie Kux,

Associate Commissioner for Policy,

[FR Doc. 2015-07018 Filed: 3/26/2015 08:45 am; Publication Date: 3/27/2015]