

ACRP Regulatory Affairs Committee Review of Notice of Public Hearing; Request for Comments

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

What is the document?

The FDA re-opened the comment period for public comments on the FDA's regulatory framework for homeopathic product regulation. The FDA is evaluating its current enforcement policies from scientific, risk and process perspectives for drug products labeled as homeopathic.

Who does it impact & how?

The FDA's re-evaluation can impact manufacturers of homeopathic drugs, the entire supply and distribution chain, evidentiary basis for claims, and of course the end consumer of homeopathic drug products.

What did ACRP RAC have to say about it?

ACRP RAC members encourage the FDA to amend the eligibility criteria for adding drugs to the Homeopathic Pharmacopoeia of the United States (HPUS). Currently the requirements for a product to be added to the HPUS is that 3 mandatory criteria must be met plus any one of an additional 4 criteria need to be met. Criterion 6 (one of the 4 optional criteria) reads "(t)he therapeutic use of the drug is established by at least two adequately controlled double blind clinical studies using the drug as the single intervention; the study is to be accompanied by adequate statistical analysis and adequate description of the symptom picture acceptable to the HPCUS which includes the subjective symptoms and, where appropriate, the objective symptomatology". ACRP recommends that this criterion be made mandatory whenever the product is intended to be used in the diagnosis, treatment, or mitigation of any disease. And further, the RAC members recommend that any existing products in HPUS that do not meet this criteria should be required to revise labeling, be reclassified, or removed from the market until adequate evidence can be presented. Enforcing this requirement will align current regulation and guidance and discourage misbranding and exaggerated claims to protect the community and credibility of homeopathic drugs.

When were the RAC's comments sent to the agency?

November 5, 2015

Where can I access this document?

<http://www.fda.gov/Drugs/NewsEvents/ucm430539.htm>



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November 5, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

In reference to docket number: **FDA-2015-N-0540-7641**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Almost 40 years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research." The Academy of Physicians in Clinical Research (APCR) is an affiliate of ACRP and is the leading professional organization, exclusive to physicians, that supports and addresses these unique issues and challenges of all physicians involved in clinical research.

ACRP appreciates the opportunity to provide the FDA with our comments on the Homeopathic Product Regulation: Evaluating the FDA's Regulatory Framework After a Quarter-Century as this issue has a significant impact on our membership.

The docket states "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 FR21728, 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 HPUS criteria for inclusion of homeopathic drugs list clinical evidence of safety and efficacy as only one of several criteria, any one of which is adequate to meet the HPUS standards. ACRP is concerned that the scientific basis for homeopathy remains questionable at best, but more importantly, any regime that does not make level one or equivalent scientific evidence of safety and efficacy to support claims a prerequisite does not confer sufficient protection to the public, nor engender confidence that any homeopathic listed in the HPUS is anything more than placebo.

Existing conflicts in Federal Trade Commission's position on homeopathic drug claims need to be supported by scientific evidence and the FDA's allowance of homeopathic



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drug marketing without efficacy data cause consumer confusion regarding the potential therapeutic effects of homeopathic drugs. The potential for serious harm exists especially when a safe and effective medical intervention is available and appropriate but the patient chooses a homeopathic option without any documented safety and efficacy. Additional harms may result from the increasing reliance of the public on questionable methods of self-diagnosis and treatment, especially when the product has no evidence of safety and efficacy and when side effects may not become obvious until after many years of low dose use which is common in homeopathic settings. History is replete with examples of questionable even harmful remedies have been allowed to be marketed, with unfortunate results for individuals, as well as society. Knowledgeable consumers choose homeopathic alternatives for specific indications, but uninformed consumers choose these remedies based on labeling claims. Only by ensuring clinical evidence to support medical claims is made a prerequisite to HPUS listing will the often naive public have the necessary protection the FDA was brought into existence to confer.

Therefore, ACRP recommends that Criterion "6) The therapeutic use of the drug is established by at least two adequately controlled double blind clinical studies using the drug as the single intervention; the study is to be accompanied by adequate statistical analysis and adequate description of the symptom picture acceptable to the HPCUS which includes the subjective symptoms and, where appropriate, the objective symptomatology" be made mandatory to support inclusion of a homeopathic drug in the HPUS, whenever it is intended for the preparation in question to be used in the diagnosis, treatment, or mitigation of any disease. Any existing products in HPUS that do not meet this criteria should be required to revise labeling, be reclassified, or removed from the market until adequate evidence can be presented. Enforcing this requirement will align current regulation and guidance and discourage misbranding and exaggerated claims to protect the community and credibility of homeopathic drugs.

We applaud the FDA's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

A handwritten signature in black ink that reads "JP Kremidas". The signature is written in a cursive, flowing style.

Jim Kremidas
Executive Director

(3) If a ferrule is installed on the rotating star, before further flight, dye-penetrant inspect the rotating star for a crack in areas "Z" depicted in Figure 1 of Airbus Helicopters ASB No. EC130 62A010, ASB No. AS350 62.00.34, or ASB No. AS355 62.00.33, all Revision 0, and all dated April 28, 2014, as applicable to your model helicopter.

(i) If the rotating star has a crack, before further flight, remove from service the rotating star; ferrule; and the screws, washers and nuts used to attach the pitch change rods, compass, and the rotating star deflector.

(ii) If the rotating star does not have a crack, within 160 hours TIS, remove from service the rotating star; ferrule; and the screws, washers and nuts used to attach the pitch change rods, compass, and the rotating star deflector.

(4) Do not install a rotating star P/N 350A371003-04, 350A371003-05, 350A371003-06, 350A371003-07, or 350A371003-08 with a ferrule.

(f) Special Flight Permit

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222-5110; email robert.grant@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

The subject of this AD is addressed in the European Aviation Safety Agency (EASA) AD No. 2014-0132R1, dated June 2, 2014. You may view the EASA AD on the Internet at <http://www.regulations.gov> in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC)
Code: 6200, Main Rotor System.

Issued in Fort Worth, Texas, on March 18, 2015.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.
[FR Doc. 2015-06805 Filed 3-26-15; 8:45 am]

BILLING CODE 4910-13-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.

ADDRESSES: 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 3-26-15; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2015-0083; FRL-9924-74-Region 9]

Revisions to the California State Implementation Plan, Placer County Air Pollution Control District and the Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Placer County Air Pollution Control District (PCAPCD) and the Ventura County Air Pollution Control District (VCAPCD) portion of

Proposed Rules

Federal Register

Vol. 80, No. 174

Wednesday, September 9, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public hearing that appeared in the **Federal Register** of March 27, 2015. In the notice of public hearing, FDA requested comments on a number of specific questions identified in the document. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice of public hearing published March 27, 2015 (80 FR 16327), and extended on June 10, 2015 (80 FR 32868). Submit either electronic or written comments by November 9, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA-2015-N-0540 for this notice of public hearing. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993-0002, 301-796-2895.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 27, 2015, FDA published a notice of public hearing with a 60-day comment period following the public hearing and requested comments on a number of specific questions identified throughout the document. Comments on the notice of public hearing will inform FDA's decision about whether and how to adjust the current enforcement policies for drug products labeled as homeopathic to reflect changes in the homeopathic product marketplace over the last approximately 25 years. In the **Federal Register** of June 10, 2015, in response to requests for an extension to allow interested persons additional time to submit comments, FDA extended the original comment period for 60 days, until August 21, 2015.

FDA is reopening the comment period for an additional 60 days, until November 9, 2015. The Agency believes that reopening the comment period for an additional 60 days for the notice of public hearing will allow adequate time for interested persons to submit comments without significantly

delaying Agency decisionmaking on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Identify 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>.

Dated: September 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-22682 Filed 9-8-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 9263]

RIN 1400-AD78

Privacy Act; STATE-75, Family Advocacy Case Records

AGENCY: Department of State.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of State is giving notice that certain portions of the Family Advocacy Case Records, STATE-75, system of records are proposed to be exempt from one or more provisions of the Privacy Act of 1974.

DATES: Comments on this rule are due by October 19, 2015.

FOR FURTHER INFORMATION CONTACT: John Hackett, Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA-2; 515 22nd Street NW., Washington, DC 20522-8001, or at Privacy@state.gov.

SUPPLEMENTARY INFORMATION: The Department of State maintains the Family Advocacy Case Records system of records. The primary purpose of this system of records is to be utilized at post by members of the Family Advocacy Team and in the Department