

# Proposed Rules

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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](mailto: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

of State by the Family Advocacy Committee. The information may be shared within the Department of State on a need to know basis and in medical clearance determinations for overseas assignment of covered employees and family members, as well as for making determinations involving curtailment, medical evacuation, suitability, and security clearance. See Public Notice 6472 (January 5, 2009) at 74 FR 330.

The Department of State is issuing this document as a notice to amend 22 CFR part 171 to exempt portions of the Family Advocacy Case Records system of records from the Privacy Act subsections (c)(3);(d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a (k)(1) and (k)(2). STATE-75 is exempted under (k)(1) to the extent that records within that system are subject to the provisions of 5 U.S.C. 552(b)(1) STATE-75 is exempted under (k)(2) to the extent that records within that system are comprised of investigatory material compiled for law enforcement purposes, subject to the limitations set forth in that section.

#### List of Subjects in 22 CFR Part 171

Privacy.

For the reasons stated in the preamble, 22 CFR part 171 is proposed to be amended as follows:

#### PART 171—[AMENDED]

■ The authority citation for part 171 continues to read as follows:

**Authority:** 5 U.S.C. 552, 552a; 22 U.S.C. 2651a; Pub. L. 95-521, 92 Stat. 1824, as amended; E.O. 13526, 75 FR 707; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

#### § 171.36 [Amended]

■ 2. Section 171.36 is amended by adding an entry, in alphabetical order, for “Family Advocacy Case Records, STATE-75” to the lists in paragraphs (b)(1) and (2).

Joyce A. Barr,

*Assistant Secretary for Administration, U.S. Department of State.*

[FR Doc. 2015-22711 Filed 9-8-15; 8:45 am]

BILLING CODE 4710-36-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 174 and 180

[EPA-HQ-OPP-2015-0032; FRL-9933-26]

### Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of filing of petitions and request for comment.

**SUMMARY:** This document announces EPA's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

**DATES:** Comments must be received on or before October 9, 2015.

**ADDRESSES:** Submit your comments, identified by the Docket Identification (ID) Number and the Pesticide Petition Number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Director, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305-7090, email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov); or Susan Lewis, Director, Registration Division (RD) (7505P), main telephone number: (703) 305-7090, email address: [RDNotices@epa.gov](mailto:RDNotices@epa.gov). The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001. As part of the mailing address, include the contact person's

name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

#### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

##### B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [www.regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help