

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

the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from the surface coating of plastic parts and products, metalworking fluids and direct-contact lubricants. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act (CAA or the Act).

DATE: Any comments on this proposal must arrive by April 27, 2015.

ADDRESSES: Submit comments, identified by docket number: EPA–R09–OAR–2015–0083 by one of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the on-line instructions.

2. *Email:* steckel.andrew@epa.gov.

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through www.regulations.gov or email.

www.regulations.gov is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: Generally, documents in the docket for this action are available electronically at www.regulations.gov and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105–3901. While all documents in the docket are listed at www.regulations.gov, some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business

hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972–3024, lazarus.arnold@epa.gov.

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: PCAPCD Rule 249 and VCAPCD Rule 74.31. In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment. We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: February 27, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–06857 Filed 3–26–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0634; FRL–9925–18–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Plan Approval and Operating Permit Fees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania pertaining to minor editorial revisions to Pennsylvania’s existing plan approval and operating permit fee rules. In the Final Rules section of this **Federal Register**, EPA is approving the State’s SIP submittal as a direct final rule without prior proposal because the Agency views this as a

noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by April 27, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2014–0634, by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email:* Campbell.Dave@epa.gov.

C. *Mail:* EPA–R03–OAR–2014–0634, Dave Campbell, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2014–0634. EPA’s policy is that all comments received will be included in the public docket without change, and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact