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) 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(h).

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.

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

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 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: stackel.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
days by April 27, 2015.

ADDRESSES: Submit comments,
identified by docket 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 electronic
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