false claim or statement would be increased from $5,000 to $7,000.

(2) The maximum and minimum penalties under the false claims provisions at 31 U.S.C. 3729(a) would be increased from $10,000 to $14,000 and $5,000 to $7,000, respectively.

(c) Imposition of the increases are limited to actions occurring after the effective date of the increases.

(d) No increase may exceed ten percent of the penalty or range of penalties, as applicable.

§ 356.2 Program Fraud Civil Remedies Act of 1986.

In the case of penalties assessed under part 355 of this chapter, an additional penalty of $500 may be assessed for claims or statements made after October 23, 1996.

§ 356.3 False claims.

In the case of penalties assessed under 31 U.S.C. 3729 based on actions occurring after October 23, 1996, the minimum penalty is $5,500 and the maximum penalty is $11,000.

Dated: September 19, 1996.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96–24544 Filed 10–22–96; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 96N–0057]

National Environmental Policy Act; Proposed Revision of Policies and Procedures; Reopening of Comment Period as to Specific Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to November 22, 1996, the comment period on specific information that supports certain categorical exclusions proposed by FDA in the proposed rule entitled ''National Environmental Policy Act; Proposed Revision of Policies and Procedures.'' The proposal was published in the Federal Register of April 3, 1996 (61 FR 14922) (republished on May 1, 1996 (61 FR 19476)). FDA is reopening the comment period for 30 days for the sole purpose of inviting public comments on those categorical exclusions for which information has been added to the administrative record.

DATES: Written comments must be received by or postmarked on or before November 21, 1996. Comments postmarked after such date will not be considered.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drugs: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5721.

For information regarding biologics: Nancy A. Roscioli, Center for Biologics Evaluation and Research (HFM–205), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031.

For information regarding veterinary medicines: Charles E. Eirkson, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1683.

For information regarding foods: Buzz L. Hoffmann, Center for Food Safety and Applied Nutrition (HFS–246), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3005.

For information regarding medical devices and radiological health: Mervin O. Parker, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 3, 1996 (61 FR 14922) (republished on May 1, 1996 (61 FR 19476)), FDA published a proposed rule to amend its regulations governing compliance with the National Environmental Policy Act of 1969 (NEPA) as implemented by the regulations of the Council on Environmental Quality. The primary purpose of the proposed rule is to increase the efficiency of FDA's implementation of NEPA and reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an environmental impact statement nor an environmental assessment (EA) is required. The proposed rule was issued in response to an initiative announced in the President's National Performance Reports, ''Reinventing Drug and Medical Device Regulations,'' April 1995, and ''Reinventing Food Regulations,'' January 1996. The proposal gave interested persons the opportunity to submit written comments until July 2, 1996.

One of the categorical exclusions included in the proposed rule is a categorical exclusion for an ''[a]ction on an NDA [new drug application], abbreviated application, or a supplement to such application, or action on an OTC [over-the-counter] monograph, if the action increases the use of the active moiety, but the concentration of the substance in the environment will be below 1 part per billion [ppb].'' (See proposed § 25.31(b) (61 FR 19476 at 19492).) The agency proposed this categorical exclusion because FDA has determined that such actions for which concentrations of the substance in the environment from use and disposal will be below 1 ppb ordinarily do not have a significant effect on the environment. If there are specific environmental concerns beyond those relating to use and disposal, for example sourcing, FDA may give a specific action further environmental consideration.

On July 2, 1996, FDA received a request from Edward Lee Rogers, on behalf of the Oregon Natural Resources Council Fund and the Oregon Natural Resources Council Action, to extend the comment period to permit comment on the ''underlying data upon which FDA relies for the claimed adequacy and appropriateness of that [1 ppb] criteria.''

FDA considered this request and has decided to add information to the administrative record and reopen the comment period. FDA has added to the administrative record a report on the ''Retrospective Review of Ecotoxicity Data Submitted in Environmental Assessments.'' This report summarizes the ecotoxicity data that supports the Center for Drug Evaluation and Research's (CDER's) proposal to categorically exclude actions on an NDA, abbreviated application, or a supplement to such application, or action on an OTC monograph, if the action increases the use of the active moiety, but the concentration of the substance in the environment will be below 1 ppb. FDA has also added to the administrative record an index of the petitions and actions that support certain categorical exclusions for foods,

food additives and color additives in the proposed rule.

The agency is reopening the comment period to ensure that the public has an opportunity to comment on the data that support the proposed categorical exclusions set forth in §§ 25.31(b) and 25.32(i), (j), (k), (l), (m), (q), and (r).

FDA believes that 30 days to comment is ample in this case, because the agency is specifically limiting its reopening of the comment period to comments on the categorical exclusions for which information has been added to the administrative record. Furthermore, data from EA's and findings of no significant impact for approved applications that support FDA's proposed categorical exclusions have always been available to the public upon request. Comments are invited, and will be considered, only to the extent they are focused on the categorical exclusions supported by information that has been added to the administrative record and only to the extent the comments regarding such information raise new issues not already raised by the person submitting the comment.

The documents that the agency is adding to the record are as follows:

1. ''Retrospective Review of Ecotoxicity Data Submitted in Environmental Assessments,'' CDER, FDA.

2. Index of Petitions and Actions Supporting Categorical Exclusions for Foods, Food Additives, and Color Additives in proposed 21 CFR part 25.

Interested persons may, on or before November 21, 1996, submit to the Dockets Management Branch (address above) written comments regarding the documents listed above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–27022 Filed 10–21–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WV017–6003b; WV040–6005b; FRL–5619–7]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia (Prevention of Significant Deterioration: NO_2 and PM–10 Increments)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve two State Implementation Plan (SIP) revisions submitted by the State of West Virginia. The first revision amends West Virginia's Prevention of Significant Deterioration (PSD) regulation by amending definitions, establishing the maximum increase in ambient nitrogen dioxide concentrations allowed in an area above the baseline concentration (the increment) and updating the references to federal air quality modeling procedures. The second revision removes increment provisions for total suspended particulates (TSP) and replaces them with increment provisions for particulate matter with an aerodynamic diameter of less than or equal to a nominal 10 micrometers (PM–10). The second revision also updates the references to federal air quality modeling procedures and adds provisions for pollution control projects at electric utilities. In the Final Rules section of this Federal Register, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial SIP revision 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 proposed rule, no further activity is contemplated in relation to this rule. 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 on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by November 21, 1996.

ADDRESSES: Written comments on this action should be addressed to Kathleen Henry, Chief, Permit Programs Section, Mailcode 3AT23, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; and the West Virginia Department of Environmental Protection, Office of Air Quality, 1558 Washington Street, East, Charleston, West Virginia, 25311.

FOR FURTHER INFORMATION CONTACT: Lisa M. Donahue, (215) 566–2062, donahue.lisa@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action of the same title which is located in the Rules and Regulations Section of this Federal Register.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 20, 1996.

Stanley L. Laskowski,

Acting Regional Administrator, Region III.

[FR Doc. 96–27005 Filed 10–21–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[LA–23–1–6871b; FRL–5636–5]

Approval and Promulgation of State Implementation Plan; Louisiana; 15 Percent Rate-of-Progress Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a revision to the Louisiana State Implementation Plan (SIP) for the purpose of satisfying the 15 percent rate-of-progress requirements of the Clean Air Act (Act) which will aid in ensuring the attainment of the national ambient air quality standard (NAAQS) for ozone.

In the final rules section of this Federal Register, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial amendment 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 proposed rule, no further activity is contemplated in relation to this rule. 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. The EPA will not institute a second comment period on this action. Any parties interested in