of Food and Drugs, it is proposed that 21 CFR parts 16 and 807 be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 807.103 to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 807.103 relating to rescission of substantially equivalent orders and rescission appeal procedures.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

3. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

4. Section 807.3 is amended by adding new paragraphs (t), (u), and (v) to read as follows:

§ 807.3 Definitions.

* * * * *

(t) *510(k) submitter* means the person who submitted the 510(k) to FDA.

(u) *510(k) holder* means the person who possesses the rights to market a device that is the subject of 510(k) substantial equivalence order.

(v) *510(k) holder* of record means the person FDA has on file as being the holder of the 510(k).

5. Section 807.103 is added to subpart E to read as follows:

§ 807.103 Rescission of 510(k) substantially equivalent orders and rescission appeal procedures.

(a) *Grounds for rescinding a substantially equivalent order.* FDA may issue an order rescinding a determination of substantial equivalence under this section, if FDA determines that any one of the following grounds exist:

(1) The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence.

(2) Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

(3) (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or

(ii) A court has issued a judicial order determining the legally marketed device(s) on which the substantial equivalence determination was based to be misbranded or adulterated.

(4) The premarket notification contained or was accompanied by an untrue statement of material fact.

(5) The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable institutional review board regulations (part 56 of this chapter) or informed consent regulations (part 50 of this chapter) in a way that the rights or safety of human subjects were not adequately protected.

(6) The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under § 812.119 of this chapter.

(b) *Notice of proposed rescission and opportunity for a hearing.* Before issuing an order rescinding a substantial equivalence order, FDA will issue the 510(k) holder of record a notice of the agency's intent to rescind the 510(k) by registered letter, together with a notice of an opportunity for an informal hearing under part 16 of this chapter. FDA will also post notice of a proposed rescission on the FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with §§ 16.24(d), 16.60(h), and 10.19 of this chapter, waive, suspend, or modify any part 16 procedure and, in accordance with this section, waive, suspend, or modify any part 807 procedure.

(c) *Failure to request a hearing.* If a 510(k) holder fails to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing, FDA will consider the failure to request a hearing a waiver of such hearing and FDA will issue a letter rescinding the order determining substantial equivalence.

(d) *Rescission order.* If the 510(k) holder does not request a hearing or if, after proceedings in accordance with this part and part 16 of this chapter are completed, the agency decides to proceed with the rescission of an order determining substantial equivalence, FDA will issue to the 510(k) holder of record an order rescinding the order determining substantial equivalence. The rescission order will state each ground for rescinding the substantial equivalence determination.

(e) *Public notice of final action.* FDA will give the public notice of the order rescinding a determination of substantial equivalence. If FDA determines not to finalize a proposed rescission, FDA will also give the public notice of this determination. These notices will be placed on FDA's home page on the Internet.

Dated: January 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1128 Filed 1–12–01; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136, 141, and 143

[FRL–6918–1]

RIN 2040–AD59

Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing action on a methods update rule that approves revised versions of test procedures (*i.e.,* analytical methods) for the determination of chemical, radiological, and microbiological pollutants and contaminants in wastewater and drinking water. The revisions concern methods published by one or more of the following organizations: American Society for Testing Materials (ASTM), United States Geological Survey (USGS), United States Department of Energy (DOE), American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF). Previously approved versions of the methods remain approved. This rule will give the analytical community a larger selection of analytical methods. Today's action also corrects typographical errors and updates references where appropriate.

DATES: Written comments must be received by March 19, 2001.

ADDRESSES: You may submit written comments either by mail or electronically. Send comments to the Methods Update Comment Clerk (W–99–21), U.S. Environmental Protection Agency, Water Docket, MC–4101, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. Submit electronic comments to *OW-Docket@epa.gov.* Please submit copies of any references cited in your comments. EPA would appreciate an original and 3 copies of your comments and enclosures (including references).

This **Federal Register** document is also available on the Internet at: *http://www.epa.gov/fedrgstr.* The record for this rulemaking has been established under docket number W–99–21. Supporting documents (including references and methods cited in this notice) are available for review at the U.S. Environmental Protection Agency, Water Docket, East Tower Basement, Room EB57, 401 M Street, SW., Washington, DC 20460. For access to the docket materials, call 202/260–3027 on Monday through Friday, excluding Federal holidays, between 9 a.m. and 3:30 p.m. Eastern Daylight Standard Time for an appointment.

Copies of final methods published by ASTM are available for a nominal cost through American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. Copies of final methods published by USGS are available for a nominal cost through the United States Geological Survey, U.S. Geological Survey Information Services, Box 25286, Federal Center, Denver, CO 80225–0425. Copies of final methods published by DOE are available for a nominal cost through the Environmental Measurements Laboratory, U.S. Department of Energy, 376 Hudson Street, New York, NY 10014–3621. Copies of Standard Methods are available for a nominal cost from the American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For information regarding wastewater methods contact Dr. Maria Gomez-Taylor, Engineering and Analysis Division (4303), USEPA Office of Science and Technology, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460 (e-mail: Gomez-Taylor.Maria@epa.gov). For information regarding drinking water methods contact Dr. Richard Reding, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (e-mail: Reding.Richard@epa.gov).

SUPPLEMENTARY INFORMATION: We are proposing to approve revisions to the Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update. Elsewhere in today's **Federal Register**, the Agency is promulgating this rule as a direct final rule without prior proposal because we view these as non-controversial revisions and do not expect adverse comments. We want to allow immediate use of the methods for compliance monitoring, and believe that it is in the public interest to do so. For further information, please see the information provided in the direct final rule which is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

If EPA does not receive adverse comment, we will not take further action on this proposal. If we receive adverse comment, we will withdraw the direct final rule (or the distinct amendment, paragraph, or section to which comments apply) and it (they) will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in making comments must do so at this time. For the various statutes and executive orders that require findings for rulemaking, EPA incorporates the findings from the direct final rulemaking into this companion notice for the purpose of providing public notice and opportunity for comment.

List of Subjects

40 CFR Part 136

Environmental protection, Analytical methods, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 143

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Water supply.

Dated: December 11, 2000.

Carol M. Browner,

Administrator.

[FR Doc. 01–179 Filed 1–12–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA 00–8633]

RIN 2127–AH96

Federal Motor Vehicle Safety Standards—Motor Vehicle Brake Fluids

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes technical modifications in two of the tests included in our standard on brake fluid, *i.e.,* the evaporation test and the corrosion test. The purpose of the modifications would be to improve the repeatability and reproducibility of the tests. This document also requests comments concerning retention of the evaporation test. A committee of the Society of Automotive Engineers, which originally developed the test, recently voted to delete the test from its standard on brake fluid. While we have tentatively concluded that the test should remain in our standard, we are requesting comments on that issue.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: You should mention the docket number of this document in your comments and submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590. Alternatively, you may submit your comments to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on ''Help & Information'' or ''Help/Info'' to obtain instructions for filing the document electronically. (This website also enables you to view the materials in the docket for this rulemaking.) You may call Docket Management at 202–366–9324. You may visit the Docket from 10 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: *For legal issues:* Edward Glancy, Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590 (202–366–2992).