operator of the affected airplane has not performed the inspection or modification.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Pilatus Aircraft Ltd.: Docket No. 95–CE–85–AD.

Applicability: Model PC–6 Airplanes (serial numbers 825 through 892).

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 75 hours time-in-service (TIS), after the effective date of this AD, unless already accomplished.

Note 2: The compliance time required in this AD takes precedence over the compliance time in Pilatus Service Bulletin PC–6 165, dated February 7, 1994.

To prevent structural failure of the hinge bracket on the horizontal stabilizer, which could result in partial or complete loss of control of the horizontal stabilizer and loss of control of the airplane, accomplish the following:

(a) Inspect the hinge brackets on the horizontal stabilizer for sheared or loose rivets in accordance with paragraph 2.A. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus Service Bulletin (SB) PC–6 165, dated February 7, 1994.

(b) Inspect the spacing tolerance of the hinge bracket in accordance with paragraph 2.C. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus SB PC–6 165, dated February 7, 1994.

(c) If there are loose or sheared rivets or if the bracket spacing is out of the spacing tolerance, prior to further flight, modify the position and space tolerance of the hinge brackets and replace any loose or sheared rivets in accordance with paragraph 2.D. in the ACCOMPLISHMENT INSTRUCTIONS section of Pilatus SB PC–6 165, dated February 7, 1994.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviations Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to Pilatus Aircraft Ltd., CH–6370 Stans, Switzerland; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri.

Issued in Kansas City, Missouri on June 4, 1996.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–14694 Filed 6–10–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 200, 250, and 310

[Docket No. 96N–0183]

RIN 0910–AA53

Consolidation of Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to consolidate a list of drugs, previously determined by rulemaking to be new drugs, into one section. This document would also remove the sections now providing for these drugs, except for certain information in the regulations that FDA considers to be necessary. This action, which will make the regulations more concise and efficient, is being taken in response to the President's regulatory reinvention initiative (REGO).

DATES: Written comments by August 26, 1996. FDA proposes that any final rule based on this proposal become effective 2 weeks after its date of publication in the Federal Register.

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: Mary E. Catchings, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–7), 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Introduction

On March 4, 1995, President Clinton issued a memorandum titled ''Regulatory Reinvention Initiative.'' This memorandum, part of the reform of the Federal regulatory system, directed heads of departments and agencies to undertake a page-by-page review of their existing regulations and to eliminate or modify those that are outdated or otherwise in need of reform. FDA has conducted a comprehensive review of

its existing regulations and has identified regulations to eliminate or modify. As a result of that review and as part of its response to the President's directive, FDA is proposing to amend or remove those parts of its drug regulations codified in Parts 200, 250, and 310 (21 CFR parts 200, 250, and 310) regarding certain drugs determined by rulemaking to be new drugs. FDA is preparing other revisions resulting from the page-by-page review for future publication.

FDA is proposing to revise § 310.502 to consolidate into one section a list of drugs that have been determined by previous rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) for which approved new drug applications under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 are required for marketing. The list would include those new drugs now codified in parts 200, 250, and 310. As the agency identifies other new drugs as being new drugs through its rulemaking procedures, FDA would add such other new drugs to the list.

Revised § 310.502 would list the names of the drugs and would not include the existing background information describing the agency's basis for determination of new drug status and, for some drugs, requirements for marketing. FDA has determined that with the exception of certain information in § 310.509 that FDA considers to be necessary, the background information no longer needs to be set out in the regulations. For some drugs, the information is outdated. For other drugs, removal of the existing explanatory text should not present a hardship or burden because the information is available from other sources. This proposal would make the regulations more concise and efficient.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this document merely proposes to consolidate existing regulations, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act no further analysis is required.

IV. Request for Comments

Interested persons may, on or before August 26, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

V. Effective Date

FDA proposes that any final rule based on this proposal be effective 2 weeks after its date of publication in the Federal Register.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 200, 250, and 310 be amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

Subpart B [Removed]

2. Subpart B, consisting of §§ 200.30 and 200.31 is removed and reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

3. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.10 [Removed]

4. Section 250.10 *Oral prenatal drugs containing fluorides intended for human use* is removed.

§ 250.103 [Removed]

5. Section 250.103 *Thorium dioxide for drug use* is removed.

§ 250.106 [Removed]

6. Section 250.106 *Cobalt preparations intended for use by man* is removed.

PART 310—NEW DRUGS

7. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

8. Section 310.502 is revised to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. Except as provided in paragraph (b) of this section, an approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

(1) Aerosol drug products for human use containing 1,1,1-trichloroethane.

(2) Aerosol drug products containing zirconium.

(3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.

(4) Camphorated oil drug products.

(5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4',5-tribromosalicylanilide), dibromsalan (DBS, 4', 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3', 4,5'-tetrachlorosalicylanilide (TC-SA)) as an ingredient in drug products.

(6) Chloroform used as an ingredient (active or inactive) in drug products.

(7) Cobalt preparations intended for use by man.

(8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.

(9) Oral prenatal drugs containing fluorides intended for human use.

(10) Parenteral drug products in plastic containers.

(11) Sterilization of drugs by irradiation.

(12) Sweet spirits of nitre drug products.

(13) Thorium dioxide for drug use.

(14) Timed release dosage forms.

(15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) Any drug listed in paragraph (a) of this section, when composed wholly or partly of any antibiotic drug, must be certified under section 507 of the act or exempted from certification under section 507 of the act for marketing.

§ 310.504 [Removed]

9. Section 310.504 *Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use* is removed.

§ 310.506 [Removed]

10. Section 310.506 *Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products* is removed.

§ 310.507 [Removed]

11. Section 310.507 *Aerosol drug products for human use containing 1,1,1-trichloroethane* is removed.

§ 310.508 [Removed]

12. Section 310.508 *Use of certain halogenated salicylanilides as an inactive ingredient in drug products* is removed.

13. Section 310.509 is revised to read as follows:

§ 310.509 Parenteral drug products in plastic containers.

(a) Any parenteral drug product packaged in a plastic immediate container is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the act, and requires an approved new drug application as a condition for marketing. An ''Investigational New Drug Application'' set forth in part 312 of this chapter is required for clinical investigations designed to obtain evidence of safety and effectiveness.

(b) As used in this section, the term ''large volume parenteral drug product'' means a terminally sterilized aqueous drug product packaged in a single-dose container with a capacity of 100 milliliters or more and intended to be administered or used intravenously in a human.

(c) Until the results of compatibility studies are evaluated, a large volume parenteral drug product for intravenous use in humans that is packaged in a plastic immediate container on or after April 16, 1979, is misbranded unless its labeling contains a warning that includes the following information:

(1) A statement that additives may be incompatible.

(2) A statement that, if additive drugs are introduced into the parenteral system, aseptic techniques should be used and the solution should be thoroughly mixed.

(3) A statement that a solution containing an additive drug should not be stored.

(d) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

§ 310.510 [Removed]

14. Section 310.510 *Use of aerosol drug products containing zirconium* is removed.

§ 310.513 [Removed]

15. Section 310.513 *Chloroform, use as an ingredient (active or inactive) in drug products* is removed.

§ 310.525 [Removed]

16. Section 310.525 *Sweet spirits of nitre drug products* is removed.

§ 310.526 [Removed]

17. Section 310.526 *Camphorated oil drug products* is removed.

Dated: June 5, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–14706 Filed 6–6–96; 11:50 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–237–FOR, #71]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Ohio regulatory program (hereinafter the ''Ohio program'') under the surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to provisions of the Ohio rules pertaining to inspections. The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [E.D.T.] July 11, 1996. If requested, a public hearing on the proposed amendment will be held on July 8, 1996. Requests to speak at the hearing must be received by 4:00 p.m., [E.D.T.], on June 26, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Field Branch chief, at the address listed below.

Copies of the Ohio program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2153

Ohio Division of Mines and Reclamation, 1855 Fountain Square Court, Columbus, Ohio 43224, Telephone: (614) 265–1076.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Telephone: (412) 937–2153.