the proposed AD, that it would take approximately 8 hours per airplane to accomplish the proposed action, and that the average labor rate is approximately $55 an hour. Parts cost approximately $214 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $503,580. AD 90-13-12, which would be superseded by the proposed action, required the same actions as is proposed, except for a revision in the service of information. Therefore, there would be no additional cost impact of the proposed AD on U.S. operators than that which is already required by AD 90-13-12.

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 "major rule" under Executive Order 12291; (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 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 91-23-04, Amendment 39-8073 (56 FR 57236, November 8, 1991), and adding the following new AD:

Fairchild Aircraft (formerly Swearingen Aircraft Corporation): Docket No. 92-CE-06-AD. Supersedes AD 91-23-04, Amendment 39-8073

Applicability: The following model and serial numbered airplanes, certificated in any category:

Model	Serial numbers
SA226-T	T201 through T275, and T277 through T291.
SA226-T(B)	T(B)276, and T(B)292 through T(B)417.
SA226-AT	AT001 through AT074.
SA226-TC	TC201 through TC419.
SA227-TT	TT421 through TT541.
SA227-AT	AT423 through AT695.
SA227-AC	AC406, AC415, AC416, and AC420 through AC777.
SA227-BC	BC762, BC764, BC766, and BC777.

Compliance: Required within the next 100 hours time-in-service after the effective date of this AD, unless already accomplished.

To prevent loss of control of the airplane because of improper operation of the power lever flight idle detent arms, accomplish the following:

(a) Modify the power level detent arms and cover assembly in accordance with the instructions in Fairchild Service Bulletin (SB) No. 226-76-008, issued January 15, 1991, revised December 17, 1991; or Fairchild SB No. 227-76-002, issued January 15, 1991, revised May 9, 1991, whichever is applicable.

(b) If the modification required by paragraph (a) of this AD has been accomplished in accordance with either Fairchild SB No. 226-76-008 or Fairchild SB No. 227-76-002, both issued January 15, 1991, revised May 9, 1991, whichever is applicable, then no further action is required by this AD.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Fort Worth Airplane Certification Office, FAA, Fort Worth, Texas 76193-0150. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth, Airplane Certification Office.

(e) All persons affected by this directive may obtain copies of the documents referred to herein upon request to the Fairchild Aircraft Corporation, P.O. Box 790490, San Antonio, Texas 78279-0490; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(f) This amendment supersedes AD 91-23-04, Amendment 39-8073.

Issued in Kansas City, Missouri, on March 5, 1992.

Larry E. Werth,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-5697 Filed 3-10-92; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 357

[Docket No. 79N-0379]

RIN 0905-AA06

Discussion of Appropriate Testing Procedures for Exocrine Pancreatic Insufficiency Drug Products; Workshop and Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Workshop and reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record and announcing that a workshop will be held to discuss testing procedures that will be required as part of new drug applications for all exocrine pancreatic insufficiency drug products. FDA is holding this workshop after considering public comments on the agency's notice of proposed rulemaking for over-the-counter (OTC) exocrine pancreatic insufficiency drug products that was published in the **Federal Register** of July 15, 1991 (56 FR 32282). The meeting will be structured to discuss the specific topics and to seek answers to the specific questions listed in this notice.

DATES: The meeting will be held on April 23, 1992, at 8:30 a.m. The meeting will last 1 day. Relevant data and notice of participation by April 10, 1992. Administrative record to remain open until July 23, 1992. Comments regarding matters raised at the meeting by July 23, 1992.

ADDRESSES: Relevant data, notice of participation, and written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Meeting to be held in Conference Rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen Cothran, or Diana Hernandez, Center for Drug Evaluation and Research (HFD-210), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8868.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 21, 1979 (44 FR 75666), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC exocrine pancreatic insufficiency drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by April 21, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by May 21, 1980.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were placed on display in the Dockets Management Branch (address above) after deletion of a small amount of trade secret information. Only five comments were submitted in response to the publication of the advance notice of proposed rulemaking.

In the Federal Register of November 8, 1985 (50 FR 46594), the agency published a notice of proposed rulemaking to establish a monograph for OTC exocrine pancreatic insufficiency drug products based on the Panel's recommendations and the agency's response to comments submitted following publication of the advance notice of proposed rulemaking. In that document, the agency accepted the Panel's recommendation that exocrine pancreatic insufficiency drug products be available as OTC drug products and proposed the conditions under which these drug products would be generally recognized as safe and effective and not misbranded. In response to this publication, 2 drug manufacturers, 2 foundations, 39 health care professionals, 2 health departments, 2 Congressmen, 2 advocacy groups, and 147 individuals submitted comments. Copies of the comments received and any additional information that has come to the agency's attention since publication of the tentative final monograph are on public display in the Dockets Management Branch.

New information submitted in response to the tentative final monograph caused the agency to reconsider the approach proposed in that document. In the Federal Register of July 15, 1991 (56 FR 32282), FDA proposed that OTC drug products used to treat exocrine pancreatic insufficiency are not generally recognized as safe and effective, are misbranded, and are 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)). The proposed rule would amend part 310 (21 CFR part 310), subpart E by adding new § 310.543 (21 CFR 310.543). Accordingly, the proposed monograph published in the Federal Register of November 8, 1985 (50 FR 46594), which would have amended part 357 (21 CFR part 357) by adding new Subpart E, was withdrawn on July 15, 1991.

The information submitted in response to the 1985 tentative final monograph and other available information prompted the agency to propose in the July 15, 1991, document that all exocrine pancreatic insufficiency drug products, whether currently marketed on a prescription or OTC basis, be considered new drugs requiring an approved application for continued marketing. No exocrine pancreatic insufficiency drug products currently have an approved application. The agency is very concerned about the effects that a pancreatic extract drug product's formulation and manufacturing process will have on the drug's safe and effective use. The bioavailability of the enzymes present in these products is dependent on the process used to manufacture the drug products. The agency has determined that this process could not be adequately addressed under the OTC drug monograph system. However, under an approved application, formulation and manufacturing issues can be resolved prior to marketing. The 1991 document also proposes that all exocrine pancreatic insufficiency drug products be marketed by prescription.

Interested persons were invited to file by November 12, 1991, written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs, as well as comments on the agency's economic impact determination. In response to this proposal, two foundations, five drug manufacturers, and three individuals submitted comments. Copies of these comments are on public display in the Dockets Management Branch.

The Cystic Fibrosis Foundation requested a meeting with agency representatives to discuss certain aspects of the proposed rule (Refs. 1, 2, and 3). A meeting was held on November 26, 1991, and the following topics were discussed: (1) Development of criteria for new drug application approval of exocrine pancreatic insufficiency drug products, (2) the clinical information that would be necessary to support efficacy claims, and (3) what manufacturing standards should be required (Ref. 4). At that meeting, FDA representatives stated that the active ingredients used in currently marketed exocrine pancreatic insufficiency drug products may be considered safe and effective, but that FDA must have data to show that the drugs provide and deliver the enzyme content that is declared on the container labeling and that the stated activity is released in the intestine to show that the drug will have bioactivity. FDA representatives stated that the important parameters are: (1) Manufacturing controls, (2) dissolution rates of the drug products, (3) in vivo release of the drug in the gut, and (4) correlation of the drug's release with its dissolution. It was agreed that a workshop would be beneficial to discuss what types of information should be provided to the agency. Accordingly, the agency is inviting all interested manufacturers of exocrine pancreatic insufficiency drug products, health professionals, and the general public to a workshop to discuss the issues related to the testing of these drug products. The following topics and questions will be considered at the workshop:

1. *Study design.* What types of studies should be conducted on exocrine pancreatic insufficiency drug products to show that the drugs provide and deliver the enzyme content that is declared on the container labeling and that the stated activity is released in the intestine to show that the drug will have bioactivity?

2. *Endpoints of study.* Comments submitted to the agency have suggested the following endpoints: (1) Average daily stool weight, (2) percent of dietary fat and protein absorbed, (3) energy lost in the stool, and (4) serum uric acid and 24 hour urinary excretion of uric acid (Ref. 5).

3. *Study population.* What populations should be studied? Do cystic fibrosis patients have to be used in the studies, or can the needed information be obtained using normal volunteers? Should data be obtained from both of these groups? Is it possible to use patients with other pancreatic insufficiency problems?

4. *Enzyme measurement.* Lipase, protease, and amylase concentrations can all be measured by in vitro assays in the manufactured product. Is the vivo measurement of each enzyme feasible, reliable, and pertinent, or should in vivo measurement of the percent of dietary fat and protein absorbed be relied upon?

5. *Manufacturing controls.* What manufacturing controls are necessary?

6. *Reference standards.* What reference products and/or reference standards are necessary and available? The United States Pharmacopeial (U.S.P.) Convention is in the process of setting new standards for exocrine pancreatic insufficiency drug products, and a U.S.P. reference standard is not currently available. What criteria are needed to establish an appropriate U.S.P. reference standard?

7. *Enzyme content and labeling.* What is the best way to assure consistency of actual enzyme content per dosage unit versus the amount declared in the product labeling? What product limits (not less than and not more than) should be allowed?

8. *Dissolution rates.* How can dissolution rates and in vivo bioavailability of the drug in the gut be measured? What is the correlation of the drug's release and activity with its dissolution profile?

In view of the many questions associated with exocrine pancreatic insufficiency drug products, the agency has concluded, under 21 CFR 10.65, that it would be in the public interest to hold a workshop to discuss these issues.

The agency requests information on the above questions from any interested person. Any individual or group wishing to submit data relevant to the questions above prior to the workshop should send them on or before April 10, 1992 to Docket No. 79N–0379, Dockets Management Branch (address above). Any individual or group wishing to make a presentation at the workshop should contact Helen Cothran or Diana Hernandez, Division of OTC Drug Evaluation (HFD–210), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8888. Interested persons who wish to participate must also send a notice of participation on or before April 10, 1992 to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this document and should contain the following information: Name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation; and the subject and approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record for the rulemaking for OTC exocrine pancreatic insufficiency drug products is being reopened to include all comments and data submitted since the record previously closed on November 12, 1991, and the proceedings of this workshop. The administrative record will remain open until July 23, 1992, to allow comments on matters raised at the workshop.

References

(1) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, August 15, 1991, Comment No. C213, Docket No. 79N–0379, Dockets Management Branch.

(2) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, September 16, 1991, Comment No. C213, Docket No. 79N–0379, Dockets Management Branch.

(3) Letter from R. Beall, Cystic Fibrosis Foundation, to Dockets Management Branch, October 21, 1991, Comment No. C203, Docket No. 79N–0379, Dockets Management Branch.

(4) Memorandum of meeting between Cystic Fibrosis Foundation and FDA, November 26, 1991, coded MM 1, Docket No. 79N–0379, Dockets Management Branch.

(5) Letter from R. Beall, Cystic Fibrosis Foundation, to S. Fredd, FDA, January 13, 1992, Comment No. Docket No. 79N–0379, Dockets Management Branch.

Dated: March 4, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–5691 Filed 3–10–92; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

42 CFR Part 411

[BPD–674–P]

RIN 0938–AF40

Medicare Program; Physician Ownership of, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: The proposed rule would incorporate into regulations the provisions of section 6204 of the Omnibus Budget Reconciliation Act of 1989, as amended by section 4207(e) of the Omnibus Budget Reconciliation Act of 1990, which provide that, if a physician or a member of a physician's immediate family has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of clinical laboratory services under the Medicare program, except under specified circumstances.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 11, 1992.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–674–P, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Due to staffing and resource limitations, we cannot accept audio or video comments or facsimile (FAX) copies of comments. In commenting, please refer to file code BPD–674–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone : (202) 245–7890).

If you wish to submit comments on the information collection requirements contained in this proposed rule, you may submit comments to: Allison Herron, HCFA Desk Officer, Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the **Federal Register** containing this document, send your request to the Government Printing Office, ATTN: New Order, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783–3238 or by faxing to (202) 512–2250. The cost for each copy (in paper or microfiche form) is $1.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register.** The order desk operator will be able to tell you the