oxygen hose located in the flight compartment gangway and the adjacent electrical wiring. In addition, it was reported that no clearance was found between the flexible oxygen hoses installed in the left-hand (LH) and right-hand (RH) side consoles and the air conditioning ducts, and there was insufficient clearance between these hoses and the adjacent electrical wiring. These conditions, if not corrected, could result in chafing of the flexible oxygen hoses and the subsequent uncontrollable loss of oxygen from the flightcrew oxygen system. It also could result in the presence of oxygen in areas where ignition is possible.

Fokker has issued Service Bulletin SBF100–35–004, dated May 17, 1995, which describes procedures for replacement of the flexible oxygen hoses with insulated hose assemblies. The insulated hose assemblies are intended to prevent chafing and damage of the hoses. The RLD classified this service bulletin as mandatory and issued Dutch airworthiness directive BLA 1995–050 (A), dated May 31, 1995, in order to assure the continued airworthiness of these airplanes in the Netherlands.

This airplane model is manufactured in the Netherlands and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, the proposed AD would require replacement of flexible oxygen hoses with insulated hose assemblies. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 21 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $1,376 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $33,936, or $1,616 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

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 proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the 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 is contained 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 the following new airworthiness directive:

Fokker: Docket 95–NM–252–AD.

Applicability: Model F28 Mark 0100 series airplanes, having serial numbers 11244 through 11321 inclusive, and 11323 through 11332 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 (c) 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 as indicated, unless accomplished previously.

To prevent an uncontrollable loss of oxygen from the flightcrew oxygen system due to chafing of the flexible oxygen hoses, which could result in the presence of oxygen in areas where ignition is possible; accomplish the following:

(a) Within 12 months or 3,000 flight cycles after the effective date of this AD, whichever occurs first, replace the flexible oxygen hoses having part number (P/N) A66152–407, located in the left-hand (LH) and right-hand (RH) side consoles with insulated tube assemblies having P/N D66127–401; and replace the flexible oxygen assemblies having P/N A66152–417, located in the flight compartment gangway with insulated tube assemblies having P/N D66127–403; in accordance with Fokker Service Bulletin SBF100–35–004, dated May 17, 1995.

(b) As of the effective date of this AD, no person shall install a hose assembly with P/N A66152–417 or A66152–407, on any airplane.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

NOTE 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

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

Issued in Renton, Washington, on March 22, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–7547 Filed 3–27–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314, 600, and 601

[Docket No. 95N–0329]

RIN 0910–AA57

Changes to An Approved Application; Proposed Rule and Draft Guidance Documents; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the proposed amendments to the biologics regulations for reporting changes to an approved application and corresponding drug regulations for submitting supplements for and reporting changes to an application for well-characterized biotechnology products. The purpose of the meeting is to solicit information and views on the agency's proposed rule addressing reporting of changes to an approved application as well as discuss the material and categories set forth in the closely related draft guidance documents.

DATES: The public meeting will be held on Friday, April 19, 1996, from 8 a.m. to 5 p.m. Submit written notices of participation, including a brief summary of the presentation and approximate time requested, by April 15, 1996. Written comments will be accepted until May 6, 1996.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Attendance may be limited to 500, which is the capacity of the auditorium. Submit written notices of participation and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA requests that persons who intend to participate notify the agency in advance. To expedite processing, written notices of participation may also be FAXED to 301–827–3843. 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. Transcripts of the meeting will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: For information regarding the meeting or to advise FDA of an intent to participate: Margaret A. Tart, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–2000, FAX 301–827–3843.

For information regarding this document: Tracey H. Forfa, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 29, 1996 (61 FR 2739), FDA announced its intent to hold a public meeting during the pendency of the comment period that ends on April 29, 1996, for the proposal to amend the biologics regulations for reporting changes to an approved application and corresponding drug regulations for submitting supplements for and reporting changes to an application for well-characterized biotechnology products (21 CFR 314.70 and 601.12). During this public meeting FDA is seeking comments on the proposed mechanisms for reporting changes to an approved application. Specifically, FDA is seeking comments on the three-category scheme for reporting changes in the product, production process, equipment, facilities, or responsible personnel. The three categories would include: (1) Supplement submission and approval prior to distribution of a product made using a proposed change that has a substantial potential to have an adverse effect on a product's safety, purity, potency, or effectiveness; (2) notification not less than 30 days prior to distributing a product made using a proposed change that has a moderate potential to have an adverse effect on a product's safety, purity, potency, or effectiveness; and (3) an annual report describing changes that have minimal potential to have an adverse effect on a product's safety, purity, potency, or effectiveness.

Further, FDA is asking for comment on the proposed three-category reporting system for biological product labeling changes. A change to a product package label, container label, or package label would require one of the following: (1) Submission of a supplement with FDA approval required prior to product distribution; (2) submission of a supplement with product distribution allowed prior to FDA approval; or (3) submission of the final printed label in an annual report. Promotional labeling and advertising would be required to be submitted under procedures found at 21 CFR 314.81(b)(3)(i).

In addition, FDA is seeking public comment on the draft guidance documents, ''Changes to An Approved Application; Draft Guidance'' and ''Draft Guidance; Changes to An Approved Application for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products,'' that were made available concurrently with the proposed rule in the Federal Register of January 29, 1996 (61 FR 2748 and 2749). FDA is seeking comments on the categorization of changes in the draft guidance documents and also on the utility of the guidance documents to applicants. FDA is not, however, intending to use this forum for additional discussion of the agency's definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product that was originally announced in the Federal Register of December 8, 1995 (60 FR 63048).

The procedures governing the meeting can be found in 21 CFR part 15. Prior to the meeting, FDA will determine the amount of time assigned to each person and the approximate scheduled time for each presentation. A schedule showing the persons making presentations will be filed with the Dockets Management Branch (address above), and mailed or FAXED to each presenter before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits. However, no participant may interrupt the presentation of another participant.

Comments received at the public meeting and written comments submitted to the Dockets Management Branch (address above) by May 6, 1996, will be considered in the review of the proposed rule and guidance documents to determine whether revisions are warranted. After careful review of the public comments, FDA intends to revise the draft guidance documents, if necessary, and publish a final rule.

Dated: March 25, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–7613 Filed 3–25–96; 4:06 pm]

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