

Rib 8, in accordance with Airbus Industrie Service Bulletin No. A300-57-6027, dated October 8, 1991, or Revision 2, dated September 13, 1994. Thereafter, repeat this inspection at intervals not to exceed 6,000 landings until the inspection required by paragraph (d) of this AD is accomplished.

New Requirements of this AD

(c) For those airplanes on which Airbus modification 08609H5276 (Airbus Service Bulletin A300-57-6033), or the modification specified in Airbus Repair Drawing R571-40588 or R571-40942, has not been accomplished: Perform HFEC inspections to detect cracks in the center spar sealing angles adjacent to Rib 8, in accordance with Airbus Service Bulletin A300-57-6027, Revision 2, dated September 13, 1994, at the later of the times specified in paragraph (a)(1) and (a)(2) of this AD, as applicable. Repeat the inspection thereafter at intervals not to exceed 2,625 landings. Accomplishment of these inspections terminates the requirements of paragraph (a) of this AD.

(1) For airplanes on which HFEC inspections have not been accomplished in accordance with AD 93-23-07: Prior to the accumulation of 4,638 total landings; or within 500 landings after the effective date of this AD, whichever occurs later.

(2) For airplanes on which HFEC inspections have been accomplished in accordance with AD 93-23-07: Within 2,625 landings after accomplishment of the last inspection performed in accordance with the requirements of paragraph (a) of this AD, or within 500 landings after the effective date of this AD, whichever occurs later.

(d) For those airplanes on which Airbus Modification 08609H5276 (Airbus Service Bulletin A300-57-6033) or the modification specified in Airbus Repair Drawing R571-40588 or R571-40942 has been accomplished: Perform a HFEC inspection to detect cracks in the center spar sealing angles adjacent to Rib 8, in accordance with Airbus Service Bulletin No. A300-57-6027, Revision 2, dated September 13, 1994, at the later of the times specified in paragraphs (d)(1) and (d)(2) of this AD, as applicable. Repeat the inspection thereafter at intervals not to exceed 2,625 landings. Accomplishment of this inspection terminates the requirements of paragraph (b) of this AD.

(1) For airplanes on which HFEC inspections have not been accomplished in accordance with AD 93-23-07: Prior to the accumulation of 5,775 landings after accomplishing the modification, or within 500 landings after the effective date of this AD.

(2) For airplanes on which HFEC inspections have been accomplished in accordance with AD 93-23-07: Within 2,625 landings after accomplishment of the last inspection performed in accordance with the requirements of paragraph (b) of this AD, or within 500 landings after the effective date of this AD, whichever occurs later.

Corrective Action

(e) If any crack is found in the center spar sealing angles, including cracking entirely through the sealing angle, during the inspections required by paragraph (a), (b), (c),

or (d) of this AD: Prior to further flight, replace the pair of sealing angles on the affected wing and cold work the attachment holes, in accordance with Airbus Repair Drawing R571-40589 or R571-40942; and perform the repetitive inspections required by paragraph (c) or (d) of this AD, as applicable.

(f) If any sealing angle is found to be cracked through entirely during the inspections required by paragraph (a), (b), (c), or (d) of this AD: Prior to further flight, perform additional inspections to detect cracks in the adjacent butt strap and skin panel, in accordance with paragraph 2.B.(5) of Airbus Service Bulletin A300-57-6027, Revision 2, dated September 13, 1994. If any crack is found in the adjacent butt strap and skin panel, prior to further flight, repair in accordance with Airbus Repair Drawing R571-40611.

(g)(1) 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.

(2) Operators may request an extension of the compliance times of this AD in accordance with the adjustment for range formula found in paragraph 1(d) of Airbus Service Bulletin A300-57-6027, Revision 2, dated September 13, 1994. The average flight time per flight cycle in hours used in this formula should be for an individual airplane. Average flight time for a group of airplanes may be used if all airplanes in the group have flight times differing by no more than 10 percent. If compliance times are based on the average flight time for a group of airplanes, the individual airplane flight times of the group must be submitted to the Manager, Standardization Branch, ANM-113, for review.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(h) 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 July 11, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF LABOR

Employment Standards Administration

20 CFR Parts 718, 722, 725, 726 and 727

RIN 1215-AA99

Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended; Notice of Public Hearing

AGENCY: Employment standards Administration, Labor.

ACTION: Proposed rule; notice of public hearing.

SUMMARY: This notice schedules a second public hearing on the proposed regulations implementing the Black Lung Benefits Act which the Employment Standards Administration (ESA) issued on January 22, 1997 (62 FR 3338-3435). The first public hearing is scheduled for June 19, 1997 in Charleston, West Virginia (62 FR 27562; 62 FR 28760).

The proposed regulations reflect the program's suggestions for change in the processing and adjudication of individual claims for black lung benefits. The proposal also revises the criteria governing the responsibility of coal mine operators to secure the payment of benefits to their employees and reflects many decisions issued by the Benefits Review Board and U.S. courts of appeals over the past thirteen years. ESA proposed these regulations with the goal of improving services, streamlining the adjudication process and updating the regulations' content. The purpose of the hearings is to receive comments on the proposed changes.

DATES: The second hearing will be held in Washington, D.C. on Tuesday, July 22, 1997 beginning at 9:00 a.m. Persons seeking to testify at the public hearing based on medical, scientific, economic or other technical evidence must file a notice of intent to appear accompanied by three copies of the evidence upon which their testimony will be based. The notice and evidence must be received by Tuesday, July 8, 1997. Any other party desiring to participate must file a notice of intent to appear by Tuesday, July 15, 1997. Any party who has not filed a notice of intent to appear may be allowed to testify, at the discretion of the Administrative Law Judge, as time permits at the end of the hearing.

ADDRESSES: The second hearing will be held in the auditorium of the Frances Perkins Building, U.S. Department of Labor, 3rd Street and Constitution Avenue, N.W., Washington, D.C. 20210.

Notices of intent to appear and accompanying evidence, if any, must be sent to James L. DeMarce, Director, Division of Coal Mine Workers' Compensation, Room C-3520, Frances Perkins Building, 200 Constitution Avenue, N.W., Washington, D.C. 20210; FAX Number 202-219-8568.

FOR FURTHER INFORMATION CONTACT: James L. DeMarce, Director, Division of Coal Mine Workers' Compensation, (202) 219-6692.

SUPPLEMENTARY INFORMATION:

Filing of Notices of Intent To Appear and Evidence Before the Hearing

The notice of intent to appear must contain the following information:

1. The name, address, organization, and telephone number of each person to appear;
2. The capacity in which the person will appear;
3. The approximate amount of time required for the presentation;
4. A brief statement of the position that will be taken with respect to the proposed regulations;
5. Whether the party intends to testify based on medical, scientific, economic or technical evidence. If so, three copies of that evidence must be attached to the notice of intent to appear.

ESA will review each notice of intent to appear in light of the amount of time requested. In those instances when the requested amount of time exceeds 20 minutes, ESA will determine, in its sole discretion, whether the amount of time requested is supported by the accompanying documentation. If not, the participant will be notified of that fact prior to the hearing.

Conduct and Nature of the Hearing

The hearing will commence at 9:00 a.m. on July 22, 1997. At that time, the presiding officer, an Administrative Law Judge, will resolve any procedural matters relating to the hearing which are delegated to his discretion in this notice. It is ESA's intent to provide interested members of the public with an opportunity to make effective oral presentations and to insure that these presentations proceed expeditiously, without procedural restraints which might impede or protract the rulemaking process. The hearing is primarily for the purpose of information gathering and therefore will be an informal administrative proceeding rather than an adjudicative one. The formal rules of evidence will not apply. The hearing is also intended to facilitate the development of a clear, accurate and complete record. Thus, questions of relevance, procedure and participation

generally will be decided so as to favor development of the record.

The order of appearance of persons who have filed notices of intent to appear will be determined by ESA. Only the Department may ask questions of witnesses. The presiding officer will make no decision or recommendation on the merits of ESA's proposal, but rather will be responsible for ensuring that the hearing proceeds at a reasonable pace and in an orderly manner. The presiding officer, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing, including the powers:

1. To regulate the course of the proceedings;
2. To dispose of procedural requests, objections and comparable matters;
3. To confine the presentations to pertinent and relevant matters; and
4. To regulate the conduct of those present at the hearing by appropriate means.

Individuals with disabilities, who need special accommodations, should contact James L. DeMarce by Tuesday, July 8 at the address indicated in this notice.

Contents of the Rulemaking Record

This rulemaking record will remain open through August 21, 1997 (62 FR 27000). A verbatim transcript of the hearing will be prepared and made a part of the record. It will be available for public inspection at the Office of the Solicitor, Division of Black Lung Benefits, 200 Constitution Avenue, NW., Suite N-2605, Washington, DC 20210. Members of the public may also arrange with the court reporter to purchase their own copies. All notices of intent to appear at the hearing and accompanying evidence, if any, will also be made a part of the record and will be available for public inspection at the above address. ESA will also accept additional written comments and other appropriate data from any interested party, including those not presenting oral testimony, until expiration of the comment period.

Signed at Washington, DC, this 12th day of June, 1997.

Gene Karp,

Deputy Assistant Secretary for Employment Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 884, and 890

[Docket No. 94N-0418]

Retaining Certain Preamendment Class III Devices in Class III

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to retain the following preamendment class III devices in class III: Lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair. Manufacturers of these referenced preamendment class III devices were requested, by an order published in the **Federal Register**, to submit a summary of, and a citation to, all information known or otherwise available to them respecting their devices, including adverse safety or effectiveness information concerning the devices that had not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA believes that these devices should remain in class III because insufficient information exists to determine that special controls would provide reasonable assurance of their safety and effectiveness, and/or these devices present a potential unreasonable risk of illness or injury.

DATES: Submit written comments by September 16, 1997. FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule.

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: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 321 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), established a comprehensive system for the regulation of medical devices intended for human