Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences Between the Foreign AD and This Proposed AD

Operators should note that, although the Spanish airworthiness directive requires modification within two months after the effective date of that airworthiness directive, this proposed AD would require accomplishment of the modification within seven months after the effective date of this proposed AD. CASA has advised the FAA that modification kits would be delivered within six months after the order date.

In developing an appropriate compliance time for this AD, the FAA considered the degree of urgency associated with addressing the subject unsafe condition and the minimum time necessary for operators to order, receive, and install kits. In light of these factors, the FAA has determined that an interval of seven months is necessary to allow time for U.S. operators to order, receive, and install modification kits from CASA. The FAA finds a compliance time of seven months for accomplishing the modification to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Cost Impact

The FAA estimates that 38 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 7 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 $400 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $31,160, or $820 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.

Regulatory Impact

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:

Construcciones Aeronauticas, S.A. (CASA): Docket 97–NM–297–AD.

Applicability: Model C–212 series airplanes, as listed in CASA Service Bulletin SB–212–27–34, dated November 22, 1993, certificated in any category.

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 (b) 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 corrosion from developing in the lower shaft and support structure of the rudder, which could result in the failure of the rudder lower shaft and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 7 months after the effective date of this AD, accomplish paragraphs (a)(1) and (a)(2) of this AD, in accordance with CASA Service Bulletin SB–212–27–34, dated November 22, 1993.

(1) Inspect the rudder lower shaft and support structure for corrosion; and, prior to further flight, repair any discrepancy found. And

(2) Modify the rudder lower shaft and support structure to prevent the entry and accumulation of water.

(b) 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, International Branch, ANM–116, 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, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(c) 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.

Note 3: The subject of this AD is addressed in Spanish airworthiness directive 06/96, dated May 21, 1996.

Issued in Renton, Washington, on March 3, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–6020 Filed 3–9–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N–0087]

General Hospital and Personal Use Devices; Classification of the Apgar Timer, Lice Removal Kit, and Infusion Stand

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the Apgar timer, lice removal kit, and infusion stand into class I. FDA is also publishing the recommendations of the General Hospital and Personal Use Devices Panel (the panel) regarding the classification of the devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying the devices. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by June 8, 1998. FDA proposes that any final regulation based on this proposal become effective 30 days 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: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. A device that is first offered in commercial distribution after May 28, 1976, and which FDA determines to be substantially equivalent to a device classified under this scheme is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

A device that was not in commercial distribution before May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed predicate device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process.

In 1980, when other general hospital and personal use devices were classified (45 FR 69678 through 69737, October 21, 1980), the Apgar timer, lice removal kit, and infusion stand were inadvertently omitted. The panel made classification recommendations for these preadmendment devices during its July 18, 1995, meeting (Ref. 1).

II. Device Descriptions

FDA is proposing the following device descriptions based on the panel's recommendations (Ref. 1) and the agency's review:

(1) The Apgar timer is a device intended to alert a health care provider that the Apgar score of a newborn infant should be taken;

(2) The lice removal kit is a comb or comb-like device intended to kill and/or remove lice and nits from head and body hair; the kit may or may not be battery operated; and

(3) The infusion stand is a stationary or movable stand intended to hold infusion fluids, infusion accessories, and related devices. The infusion stand may be used to hold other medical devices.

III. Recommendations of the Panel

In the public meeting held on July 18, 1995, the panel unanimously recommended that the Apgar timer, lice removal kit, and infusion stand be classified into class I (general controls). The panel also recommended that the devices should be exempted from premarket notification submission procedures (section 510(k) of the act). The panel further recommended that the lice removal kit and infusion stand should be exempted from the current good manufacturing practice (CGMP) requirements (section 520(f) of the act (21 U.S.C. (360j)(f))), with the exception of other requirements concerning reports (§ 820.180 (21 CFR 820.180)) and complaint files (§ 820.198 (21 CFR 820.198)). The panel recommended that the Apgar timer should be exempt from the CGMP requirements and from other requirements concerning records and reports (section 519 of the act (21 U.S.C. 360i)).

IV. Summary of the Reasons for the Recommendations

The panel concluded that the safety and effectiveness of the Apgar timer, lice removal kit, and infusion stand can be reasonably ensured by general controls. Specifically, the safety and effectiveness of the lice detector kit and infusion stand can be reasonably ensured by the general controls of: (1) Registration and listing (section 510 of the act) and (2) the general requirements concerning reports (§ 820.180) and complaint files (§ 820.198); and the safety and effectiveness of the Apgar timer can be reasonably ensured by registration and listing (section 510 of the act).

V. Risks to Health

The panel identified no specific risks associated with the use of the Apgar timer, lice removal kit, or infusion stand.

VI. Summary of the Data Upon Which the Proposed Recommendation is Based

The panel based its recommendations on expert testimony presented to the panel and on the panel members' personal knowledge of and clinical experience with the Apgar timer, lice removal kit, and infusion stand.

VII. FDA's Tentative Finding

FDA tentatively concurs with the recommendations of the panel that the Apgar timer, lice detector kit, and infusion stand should be classified into class I (general controls). FDA believes that sufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of these devices.

After the panel meeting, on November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(l) to the act. Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereafter ''reserved criteria''). FDA believes that these devices do not meet the reserved criteria

and, therefore, will be exempt from premarket notification under section 510(l) of the act.

FDA, however, disagrees that the lice detector kit and infusion stand should be exempt from the CGMP requirements (section 520(f) of the act). FDA's believes that the CGMP requirements are necessary to ensure product quality. FDA believes, however, that the Apgar timer is a very simple device that may be exempted from the CGMP regulations

Consistent with the purpose of the act, class I (general controls), as defined by section 513(a)(1) of the act, would provide the least amount of regulation necessary to reasonably ensure that current and future Apgar timers, lice removal kits, and infusion stands are safe and effective.

The agency, therefore, proposes to classify the Apgar timer, lice removal kit, and infusion stand into class I in 21 CFR part 880 (general hospital and personal use devices).

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General Hospital and Personal Use Devices Panel, 30th meeting, meeting and transcript minutes, July 18, 1995.

IX. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification 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.

X. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. For these three devices, FDA is proposing that they be classified into class I, the lowest level of control allowed. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Comments

Interested persons may, on or before June 8, 1998 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.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 880 be amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.2930 is added to subpart C to read as follows:

§ 880.2930 Apgar timer.

(a) *Identification*. The Apgar timer is a device intended to alert a health care provider that the Apgar score of an new born infant should be taken.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

3. Section 880.5960 is added to subpart F to read as follows:

§ 880.5960 Lice removal kit.

(a) *Identification*. The lice removal kit is a comb or comb-like device intended to kill and/or remove lice and nits from head and body hair. It may or may not be battery operated.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 880.6990 is added to subpart G to read as follows:

§ 880.6990 Infusion stand.

(a) *Identification*. The infusion stand is a stationary or movable stand designed to hold infusion fluids, infusion accessories, and related devices. The infusion stand may be used to hold other medical devices.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: February 27, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–6150 Filed 3–9–98; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 243, 250, and 290, and 43 CFR Part 4

RIN 1010–AC21 and AC08

Administrative Appeals Process and Policy for Release of Third-Party Proprietary Information

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of a public workshop.

SUMMARY: The Minerals Management Service (MMS) is announcing a second public workshop to discuss plans to revise its regulations governing MMS's administrative appeals and alternative dispute resolution processes, including authority for disclosure of third-party proprietary information. The revisions are based in large part on a report and recommendations from the Royalty Policy Committee, which provides advice to the Secretary of the Interior under the authority of the Federal Advisory Committee Act. Interested