''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) 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 final 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, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 USC 106(g), 40113, 44701.

§39.13 [Amended]

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

97–20–11 Socata—Groupe Aerospatiale: Amendment 39–10148; Docket No. 97–CE–15–AD.

Applicability: Model TBM 700 airplanes (serial numbers 1 through 109), certificated in any category, that do not have the main landing gear (MLG) inboard doors and the door locking control mechanism removed (MOD 70–065–32) in accordance with the Technical Instruction of Modification OPT70 KO59–32, dated December 1995, as referenced in Socata Service Bulletin (SB) 70–073, Amdt. 1, dated June 1996.

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 (d) 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 100 hours time-in-service after the effective date of this AD or within the next 6 calendar months after the effective date of this AD, whichever occurs first, unless already accomplished.

To prevent the MLG from failing to extend because of corroded MLG inboard locking hinges, which could result in loss of control of the airplane during landing operations, accomplish the following:

(a) Remove the MLG inboard doors and the door locking control mechanism (MOD 70–065–32) in accordance with the Technical Instruction of Modification OPT70 KO59–32, dated December 1995, as referenced in Socata SB 70–073, Amdt. 1, dated June 1996.

(b) As of the effective date of this AD, no person may undo MOD 70–065–32 on any affected airplane, by reinstalling the MLG inboard doors and the door locking control mechanism.

(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.

(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, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. 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 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(e) The removal required by this AD shall be done in accordance with the Technical Instruction of Modification OPT70 KO59–32, dated December 1995, as referenced in Socata Service Bulletin 70–073, Amdt. 1, dated June 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or the Product Support Manager Socata—Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(f) This amendment (39–10148) becomes effective on November 13, 1997.

Issued in Kansas City, Missouri, on September 24, 1997.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–25832 Filed 9–29–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. The rule requires labeling of medical devices containing natural rubber latex that contacts humans to state: ''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''; labeling of medical devices containing dry natural rubber that contacts humans to state: ''This Product Contains Dry Natural Rubber.''; labeling of medical devices containing natural rubber latex in their packaging that contacts humans to state: ''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''; labeling of medical devices containing dry natural rubber in their packaging that contacts humans to state: ''The Packaging of This Product Contains Dry Natural Rubber.''; and that the claim of hypoallergenicity be removed from the labeling of medical devices that contain natural rubber. These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber.

EFFECTIVE DATE: This final rule is effective September 30, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–443–2444, FAX 301–443–2296.

SUPPLEMENTARY INFORMATION:

I. Background

Natural latex is a milky fluid obtained in commercial quantities primarily from the *Heavea brasiliensis* (rubber) tree. There is often confusion concerning the terminology used to describe the raw agricultural materials derived from rubber-producing plants; products made from various intermediate forms of the

raw agricultural material (e.g., natural rubber latex, dry natural rubber); formulations of synthetic latex and synthetic rubber to which natural rubber has been added; and synthetic rubber and synthetic latex formulations that do not contain natural rubber.

''Natural latex,'' for the purposes of this rule, is defined as a milky fluid that consists of extremely small particles of rubber obtained from plants, principally from the *H. brasiliensis* (rubber) tree, dispersed in an aqueous medium. It contains a variety of naturally occurring substances, including cis-1,4-polyisoprene in a colloidal suspension (Ref. 1) and plant proteins, which are believed to be the primary allergen (Refs. 2, 3, and 4).

''Natural rubber,'' for the purposes of this rule, includes all materials made from or containing natural latex. Products that contain natural rubber are made using two commonly employed manufacturing processes, the natural rubber latex (NRL) process, and the dry natural rubber (DNR) process.

The NRL manufacturing process involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating, and are typically referred to as containing or made of ''natural rubber latex.'' Examples of products that may contain natural rubber latex include medical gloves, catheters, tracheostomy tubes, and condoms.

The DNR manufacturing process involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping. These products are typically referred to as containing or made of dry natural rubber or ''crepe'' rubber. Examples of products that may contain dry natural rubber include syringe plungers, vial stoppers, and injection ports on intravascular tubing.

The phrase, ''contains natural rubber,'' as used herein, also includes products described as made of ''synthetic latex'' or ''synthetic rubber'' that include natural rubber in their formulations. This rule does not apply to products made from synthetic latex or synthetic rubber that do not include natural rubber in their formulations.

FDA has noted an increase in the number of reports submitted to its medical device reporting system regarding sensitivity to natural latex proteins contained in medical devices, including deaths following barium enemas. These deaths were associated with anaphylactic reactions to the natural rubber latex cuff on the tip of barium enema catheters. Scientific studies and case reports have documented sensitivity to natural latex proteins found in a wide range of medical devices (see Refs. 2 through 23).

Based upon this information, the agency published a proposed rule on June 24, 1996 (61 FR 32618), to require labeling statements on medical devices containing natural rubber that contact humans. This final rule is based upon comments submitted in response to the June 24, 1996 proposed rule.

II. Highlights of the Final Rule

A. Natural Rubber-Containing Devices; Labeling

FDA is requiring the labeling for medical devices containing natural rubber that contacts humans to include a statement regarding the presence of natural rubber. The agency is issuing this rule because medical devices composed of natural rubber, or which contain components formulated from natural rubber, may pose a significant health risk to some consumers or health care providers who are sensitized to natural latex proteins. A statement in the labeling of medical devices identifying the presence of natural rubber latex is considered to be necessary for the safe and effective use of such devices.

''Contacts humans,'' for the purposes of this rule, means that the natural rubber contained in a medical device is intended to contact or is likely to contact the user or patient. This includes contact when the natural rubber containing device is connected to the patient by a liquid path or an enclosed gas path; or the natural rubber containing device is powdered, and the powder may carry natural latex proteins that may contaminate the environment of the user or patient.

The device may bear one or more of four labeling statements depending on the type of natural rubber in the device and depending on whether the natural rubber is in the device itself or in its packaging. The reasoning for requiring one or more of four separate statements is discussed more fully in comments 3 and 6 in section III of this document.

Medical devices containing rubber produced by the NRL process that contacts humans shall bear labeling with the following statement in bold print: ''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.'' Representative examples of devices that contain NRL include: Cuffed enema/enterolysis catheters, latex condoms (with or without spermicidal lubricant), wound drains, cuffed airways, latex surgical gloves, and latex examination gloves.

The agency is also requiring that medical devices containing rubber produced by the DNR process that contacts humans include the following statement in bold print in their labeling: ''This Product Contains Dry Natural Rubber.'' Representative examples of devices that contain DNR include: Anesthesia masks, electrode pads, contraceptive diaphragms, crutch pads and tips, wheelchair tires, elastic components of bandages/face masks, syringe plungers, parenteral drug vial stoppers, and intravenous injection ports.

The agency is further requiring medical devices having packaging that contains natural rubber that contacts humans bear labeling with one of the following statements in bold print: ''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.'' or ''The Packaging of This Product Contains Dry Natural Rubber.'', as appropriate. The purpose of such statements is to inform individuals who are sensitive to natural rubber about the presence of natural rubber in the packaging of devices that may be, by themselves, natural rubber-free.

B. Hypoallergenicity

FDA believes that it is also necessary to prohibit certain labeling statements on medical devices that contain natural rubber. FDA believes that the labeling statement ''hypoallergenic,'' traditionally used with respect to medical gloves, cosmetics, and other products produced for individuals with chemical allergies, is interpreted by consumers to mean that the risk of allergic reactions to any component of the device would be minimal. This is not the case with devices that contain natural rubber. FDA has received reports of allergic reactions to medical gloves labeled as ''hypoallergenic.''

Use of the ''hypoallergenic'' label has been based on results of the modified (human) Draize test. While this test may be appropriate for detecting sensitization to residual levels of processing chemicals, the test does not detect sensitivity to natural latex proteins.

Thus, there is no reasonable assurance that the risk of allergic reactions to products that contain natural rubber, yet have reduced levels of processing chemicals, will be reduced for individuals who are sensitive to natural latex proteins. Therefore, the agency believes that the term ''hypoallergenic'' on the labeling of a device that contains natural rubber is misleading in that it

incorrectly implies that such device may be used safely by persons sensitive to natural latex proteins. For these reasons, FDA is requiring that the hypoallergenic claim be removed from the labeling of devices that contain natural rubber.

C. Effects of This Regulation on Premarket Submission Requirements

FDA will not require a new submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) based upon labeling changes made to comply with this rule, provided that no other changes requiring a new 510(k) submission under 21 CFR 807.81 are made to the device. Devices subject to an approved premarket approval application, however, must submit any change to the device labeling that is required by this rule in the next interim report under 21 CFR 814.39(e). Combination products that have device and drug components but are regulated under drug premarket approval provisions shall indicate the labeling change in a supplement for changes that may be made before FDA approval, as required by 21 CFR 314.70(c). Combination products that have device and biological components, but that are regulated under the biologic premarket approval provisions, shall inform the agency of the labeling change in the manner described under 21 CFR 601.12.

III. Summary of Comments

The agency received 62 comments, all of which supported the principle of natural rubber labeling for the protection of natural rubber sensitive individuals. The comments, however, differed greatly in their specific approaches.

1. A few comments suggested using the term ''crepe rubber,'' instead of ''dry rubber,'' and suggested using the term ''synthetic rubber'' instead of ''synthetic latex.''

The agency agrees that ''synthetic rubber'' should be used to describe components of certain natural rubber products covered by this regulation and has added that term in the definition of ''natural rubber'' in § 801.437(b) (21 CFR 801.437(b)). Although the agency has discussed the meaning of crepe rubber in the preamble to this regulation, the agency does not agree that the term ''crepe rubber'' should be used in place of ''dry natural rubber'' in the regulation because the agency believes the term ''dry natural rubber'' is the term most commonly used to describe rubber manufactured by the DNR process.

2. One comment pointed out that there are other sources of natural rubber besides that identified in the preamble of the proposed rule, the *H. brasiliensis* tree.

The agency agrees and has clarified in the preamble of this regulation that there are other sources of plant-derived natural rubber used in the manufacture of devices that are subject to this rule. The preamble notes that the *H. brasiliensis* tree is the primary source of commercial natural latex, instead of the only source.

3. Several comments claimed that there is no information to suggest that dry natural rubber has caused allergic reactions in individuals sensitive to natural latex proteins; therefore, dry natural rubber should not be included in the labeling requirement.

The agency recognizes that there are lower levels of natural latex proteins in products produced by the dry natural rubber process. The agency, however, does not agree that there is no information to suggest that dry natural rubber has caused allergic reactions in individuals sensitive to natural latex proteins. To the contrary, there are numerous reports that levels of natural latex proteins found in dry rubber can cause allergic reactions (Refs. 24 through 27). Accordingly, the agency has concluded that it is in the best interest of the public health to provide labeling information that a product contains dry natural rubber, so that individuals who are sensitive to the levels of natural latex proteins found in dry natural rubber may make an informed decision regarding the use of the product.

While the agency believes that persons who may respond to the levels of natural latex proteins found in dry natural rubber need to be informed of the dry rubber content in a device, the agency does not believe that those individuals need to be informed of the health consequences associated with dry natural rubber. Because allergy is a dose-response phenomenon, persons who may react to natural latex protein levels found in dry rubber would have already experienced previous allergic reactions to the higher levels of natural latex proteins found in natural rubber latex products (see Ref. 28). Therefore, those individuals would generally be aware that dry natural rubber may cause them to suffer an allergic reaction. Accordingly, FDA is requiring that products that contain only dry rubber have labeling that informs consumers of the dry rubber content, but is not requiring that such products bear labeling that states the potential health consequences from the use of the product. Therefore, FDA is requiring in the final regulation, § 801.437(e), that devices that contain dry natural rubber bear labeling with the following statement: ''This Product Contains Dry Natural Rubber.''

Persons who would not react to the levels of natural latex proteins found in dry rubber, but would react to the higher levels of natural latex proteins found in natural rubber latex products, however, may never have been aware of previous allergic reactions (Ref. 28). These persons, therefore, need to be advised of the potential health consequences of natural rubber latex products. Accordingly, FDA is requiring products containing natural rubber latex to carry labeling that states the potential health consequences of such products, as well as a natural rubber latex content statement. Therefore, FDA is requiring in the final regulation, § 801.437(d), that devices containing natural rubber latex have labeling with the following statement in bold print: ''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement is also required if a device contains both natural rubber latex and dry natural rubber that may contact humans. In this instance, the single statement will serve to advise a person who may not be aware that natural rubber may cause reactions, and will also advise a person who is aware of his or her sensitivity to natural rubber that the product contains an ingredient that may cause a reaction.

4. Some comments claimed that the applicability of the labeling statement to devices that contain natural rubber ''that may directly or indirectly contact humans'' is overly broad. One comment suggested that the labeling statement be required only on devices that have an ''intended use'' that may lead to contact with humans. Other comments suggested the statement be limited to devices which would directly contact tissues.

The agency does not believe that the application of the labeling statement to devices that contain natural rubber ''that may directly or indirectly contact humans'' is overly broad. Latex proteins may elicit an allergic reaction in individuals who are sensitive to natural rubber, even if the proteins are introduced to the individual through an indirect route. The agency, however, recognizes that the term ''indirect contact'' may be interpreted more broadly than the agency intends. Therefore, in order to avoid confusion, the agency has modified the regulation to require the labeling statements only if the natural rubber contacts humans. The final regulation, § 801.437(b), defines the term ''contacts humans'' to mean that the natural rubber contained

in a device is intended to contact or is likely to contact the user or patient (e.g., latex medical gloves or latex enema tips). This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path (e.g., intervenous administration sets, or blood collection or transfusion tubing with natural rubber injection ports, injection syringes with natural rubber plungers, or natural rubber tubing or connector components used in anesthesia or endoscopic insufflator circuits). This also includes contact when the device that contains natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient (e.g., latex tourniquets). This definition makes it clear that the labeling statement is required on devices that have an intended use that could reasonably be expected to introduce natural latex proteins to humans.

5. Several comments suggested that the natural rubber labeling statement be expanded to apply to nonmedical natural rubber latex gloves and other consumer products that contain natural rubber. Other comments suggested that medical devices sold over-the-counter (OTC) to the consumer be exempt from the labeling requirements in order to avoid confusion regarding the natural rubber-content of other consumer goods that would not be subject to this labeling regulation.

The agency disagrees that the regulation should apply to nonmedical natural rubber latex gloves and other consumer products that contain natural rubber. The regulation of such products is beyond the scope of this rule. FDA's authority under the act to impose labeling requirements is restricted to products that meet the definition of foods, drugs, cosmetics, animal drugs, biologics, and devices, as those terms are defined under the act. This rule applies to devices as defined under section 201(h) of the act (21 U.S.C. 321(h)). Under section 201(h) of the act, a device is:

> * * * an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals * * *, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Latex gloves and other products are subject to this rule, only if they meet the definition of device under section 201(h) of the act. Latex gloves that are not used in the cure, mitigation, treatment or prevention of disease are not devices within the meaning of section 201(h) of the act, and, therefore, are not subject to this rule. Latex medical gloves that are subject to this regulation include surgeon's gloves, as classified at 21 CFR 878.4460, and patient examination gloves, as classified at 21 CFR 880.6250.

FDA also does not agree with the suggestion that OTC medical devices be exempted from the labeling requirements in order to avoid confusion with natural rubber products that are not subject to this rule. The purpose of the labeling requirement is to provide essential information for individuals sensitive to natural latex proteins. An individual who is sensitive to natural latex proteins is equally likely to react to an OTC device that contains natural rubber, as to a prescription device that contains natural rubber. Therefore, it is equally important to provide essential information about OTC devices that contain natural rubber, as it is to provide information about prescription devices that contain natural rubber. Moreover, the agency does not believe that labeling, as required by this rule, on OTC devices, will cause significant confusion regarding the natural rubber content of consumer products that are not devices.

6. Several comments requested clarification on the applicability of the requirements to certain devices. Specifically, the comments asked whether the rule would apply to: Bandages with natural rubber in the adhesive; natural rubber-free devices packaged in a wrapper using natural rubber in the adhesive, especially where the adhesive would contact human tissue while unwrapping the device; foods or natural rubber-free devices handled or applied with natural rubber latex gloves; covered elastic stretch bands used to attach an accessory or component to a device; or, devices intended to contact only subcutaneous tissue.

A labeling statement is required for devices that contain natural rubber when the natural rubber contacts humans, as described in § 801.437(b) of the final rule. Accordingly, devices intended to contact subcutaneous tissue would be required to bear the appropriate statement.

Moreover, bandages with natural rubber in the adhesive would require the labeling statement. For this product, the natural rubber is intended to be applied directly to the skin. If natural rubber-containing adhesives in tapes, bindings, and similar items are intended to contact, or are likely to contact, the user or the patient, they are required to be labeled under this regulation. Covered elastic bands would not be considered to be in contact with humans, provided the covering blocks the migration of natural rubber proteins to the patient and user.

FDA does not believe it would be appropriate to require natural rubber labeling statements for natural rubber-free devices or foods that may be handled with latex gloves. As described previously in comment 5 of this document, requiring natural rubber labeling for products, such as foods, that are not devices is beyond the scope of this regulation. Moreover, FDA does not believe that requiring products that are handled by latex gloves, regardless of whether such products could be within the scope of this regulation as devices, is appropriate if such products do not contain natural rubber. Requiring labeling on products that may or may not come into contact with latex gloves would confuse consumers and would be impracticable to implement. Furthermore, FDA is not aware of any reports of allergic reactions to rubber-free products that latex gloves have contacted.

Under the final rule, natural rubber-containing packaging adhesives that typically are in areas that hold the flaps of packaging together would meet the criteria to subject the product to this rule only if they contact the patient or user. However, the agency is not aware of any evidence or reports of reactions to packaging adhesives. Given the pervasiveness of the use of adhesives that contain some amount of natural rubber latex, the lack of evidence that these adhesives cause adverse reactions, and the ability to open packaging with adhesives without coming into contact with the adhesives, the agency concludes that the adhesives in device packaging are not intended to contact humans and are not likely to contact humans. Therefore, if such adhesives are the sole source of natural rubber in the device packaging or the device itself, a device with such packaging would not be subject to this rule.

The agency stresses, however, that it considers device packaging to be an integral part of a device. Under section 201(h) of the act, a device includes any components, parts, or accessories. As an accessory to a device, the packaging is a device under section 201(h) of the act. A device that contains natural rubber in

its packaging, beyond that found in the adhesive (e.g., a device packaged in a latex sheath) is likely to contact the user or patient and must be labeled as containing natural rubber.

In order to avoid confusion and to clarify to the consumer whether it is the device itself or its packaging that contains natural rubber, however, the agency believes that a distinct labeling statement is appropriate for devices that have packaging that contains natural rubber that contacts humans. Accordingly, under § 801.437(f) and (g) of the final regulation, such devices shall have labeling with one of the following statements: ''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.'' or ''The Packaging of This Product Contains Dry Natural Rubber.''

The agency notes that if one of these packaging statements is required, it shall appear regardless of whether there is a natural rubber statement relating to the product itself. For example, a device that contains dry natural rubber that contacts humans and is also packaged in dry natural rubber that contacts humans shall be labeled with both the statements: ''Caution: The Packaging of This Product Contains Dry Natural Rubber.'' and ''This Product Contains Dry Natural Rubber.''

7. Several comments suggested that the labeling statements be required only on finished medical devices, and that device components be exempt.

The agency agrees in part. The regulation applies to all finished devices and components that are intended to contact or are likely to contact the user or patient. The labeling statement does not apply to components shipped directly to a manufacturer or processor for use in the manufacture of a device because these components, during the time before distribution to consumers, would not be intended to contact, or likely to contact the user or patient. Under these circumstances, the parts or components are not accessible to health care workers or patients. If, however, a device component is sold directly to a consumer, including a patient or health care worker, and it is intended to contact or likely to contact a user or patient, it is required to be labeled under this regulation, regardless of whether it must be attached, inserted, or used in conjunction with other devices. Replacement parts marketed as accessories for medical devices that are intended to contact or likely to contact a user or patient also require the labeling statement.

8. One comment suggested that in vitro diagnostic devices be exempt because only dry natural rubber is used, there is usually no patient contact with the natural rubber components, and space is very limited for labeling. One comment suggested that other devices that do not contact the patient be exempted, regardless of whether the natural rubber contacts the tissues of the health care worker.

The agency believes that in vitro diagnostic devices should be exempt only to the extent that the natural rubber used in vitro diagnostic devices is not intended to contact or is not likely to contact the user or the patient. FDA, however, is requiring labeling for such devices if they are intended to contact or are likely to contact health care workers or other users, as well as the patient, because all latex-sensitive persons who use the device need to be informed of the product's natural rubber content.

9. One comment requested an exemption for the labeling of natural rubber latex condoms because such condoms clearly contain latex. The comment also believed an exemption should apply to latex condoms because space for labeling is limited, a warning regarding allergic reactions may have a chilling effect on the use by individuals who are not sensitive to natural rubber, and the statement may lead to confusion in differentiating between latex and natural skin condoms because natural skin condoms also contain some natural rubber latex and would require the statement as well.

The agency disagrees and will require latex condoms to bear a labeling statement that the product contains natural rubber latex that may cause allergic reactions. Even though consumers may be aware that the product contains latex, FDA believes that the additional information that natural rubber latex may cause allergic reactions is essential information to individuals who are not aware that natural rubber latex may cause allergic reactions. The agency believes that there is sufficient room on condom packaging for the required statement.

FDA does not believe that the statement will have a chilling effect on the use of condoms by individuals who are not sensitive to natural latex proteins. The statement, however, would clearly provide important information to individuals who are sensitive to natural latex proteins.

The agency further disagrees with the suggestion that the labeling statement would be required on natural skin condoms, and thereby confuse consumers with respect to the differences between latex and natural skin condoms. Although natural skin condoms do contain a natural rubber elastic band, this band is wrapped within the natural skin sheath, and there is no evidence to indicate that the natural rubber ever contacts the user. Therefore, natural skin condoms that have a latex component that is not intended to contact or likely to contact the user do not require the labeling statement. Accordingly, the absence of any latex labeling requirement for natural skin condoms obviates the comments concern about confusion that may result from latex labeling statements on both latex and natural skin condoms.

10. Although most comments supported the requirements of standard labeling requirements, some comments suggested that the proposed labeling statements were overly prescriptive, and that manufacturers should have wide latitude in the wording of the statement provided it contain a general latex ingredient statement. Other comments stated that the labeling statements did not provide sufficient warnings, and suggested that the agency require a caution stating that use of the device may lead to chronic asthma, dermatitis, or even anaphylactic shock and death.

The agency does not agree with comments suggesting the labeling should state possible reactions with specificity. FDA believes that the statement advising consumers that a product may cause an allergic reaction is specific enough to provide adequate warning.

The agency also does not believe that the required labeling statements are overly prescriptive and that manufacturers should be given wide latitude in the wording of labeling statements. The agency has determined that requiring standardized statements for devices containing natural rubber is the best approach for providing the essential information in a clear, consistent, and accurate manner.

FDA realizes that there may be some circumstances where it may be appropriate to tailor specific information concerning a device. If a manufacturer believes use of statements that vary from those prescribed by this regulation is appropriate, § 801.437(i) of the final regulation provides that the manufacturer may petition the agency for an exemption or variance from these requirements by submitting a citizen petition under 21 CFR 10.30. Unless the agency has specifically granted an exemption or variance, the agency will consider any variation from the required statement to be noncompliant, and the device will be deemed misbranded.

11. Several comments suggested that the agency recommend the use of

natural rubber-free devices, or require a labeling statement that nonnatural rubber alternatives are available. In contrast, some comments supported natural rubber labeling provided that the label be ''ergonomically equitable'' (sic) (i.e., not giving natural rubber-free devices a perceived advantage).

The agency does not recommend the use of one legally marketed device over another. Rather the agency is requiring that labeling for devices that contain natural rubber provide information upon which an individual may make an informed choice regarding the use of the device. The benefits of devices that contain natural rubber are well established, and the agency does not intend to discourage their use by persons who are not sensitive to natural rubber. Therefore, the agency will not require the labeling statement to recommend the use of rubber-free devices.

Furthermore, because the agency is not requiring a statement that recommends the use of natural rubber-free devices, the agency does not believe that this rule gives natural rubber-free devices an advantage over devices that contain rubber. Accordingly, the agency does not believe that further modifications to the required statements are necessary to address comments that suggested the labeling not give the impression that natural rubber-free products have an advantage over products that contain natural rubber.

12. One comment requested clarification on the labeling of combination products consisting of drugs that are packaged in device container vials with dry natural rubber stoppers.

This final regulation provides authority to require natural rubber labeling on all devices containing natural rubber, including devices that are contained within combination products. As discussed in more detail in this comment, FDA intends to apply the natural rubber labeling requirement to combination products, such as drugs in device containers that are regulated currently under drug authorities.

In a final rule that published in the **Federal Register** of November 21, 1991 (56 FR 58754), the agency explained that ''the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic * * *'' or two or more different regulated entities that are produced together as a single entity, packaged together, or used together to achieve the intended effect (see 21 CFR 3.2(e)). The fact that a single product contains two or more regulated entities does not in itself change the regulatory status of the individual entities.

Because the entities that comprise a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to the product. The agency, for example, has applied both drug and device authorities, and both biological and device authorities, to certain combination products. (See Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the Drug/Device Agreement (Ref. 29)), and Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health (the Biologics/Device Agreement (Ref. 30)) (hereinafter referred to collectively as the Intercenter Agreements).)

Device container vials with dry natural rubber stoppers, when used in combination with a drug product, may be subject to regulation under the statutes and regulations applicable to devices. A vial that has a natural rubber stopper meets the definition of a device under section 201(h) of the act, in that such vial is ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or some other similar or related article, including any component, part, or accessory * * *'' that is intended to cure, mitigate, treat, or prevent disease, which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The agency regulates these empty vials, as well as other empty drug or biologic containers (such as stoppered vials for use in blood collection, intravenous containers, and blood bags), as devices.

When the drug is contained in a vial, however, the result is a combination product. The combination status of devices that serve as containers for drugs is specifically recognized in the Drug/Device Agreement. (See Ref. 29, p. 14.) To date, these combination products have been regulated only under the drug authorities (*Id*).

The agency intends to require that all combination products that contain natural rubber device components be labeled in accordance with this regulation. Although the agency could require all combination natural rubber products to comply with the regulation on its effective date, this regulation will be applied as follows: Natural rubber combination products that are currently listed in the Intercenter Agreements as being regulated under device labeling provisions will be required to comply with this rule on its effective date; natural rubber combination products that are listed in the Intercenter Agreements as being regulated under drug or biologic labeling provisions, however, will be subject to this regulation at the time of the effective date of this regulation, or at the time the Intercenter Agreements are amended to provide that these types of combination products are subject to this labeling regulation, whichever is later. FDA will provide notice in the **Federal Register** of the amendments to the Intercenter Agreements to apply this natural rubber labeling provision to all combination products that contain natural rubber device components.

At this time, the agency anticipates that the Drug/Device Intercenter Agreement will be amended to reflect that prefilled drug vial containers, transdermal patches, infusion pumps, and prefilled syringes that presently are regulated under drug authorities are also subject to this regulation. The agency believes, however, that this requirement will not affect many drug vial containers, because most drug stoppers are not being manufactured from dry natural rubber.

13. A few comments requested clarification on the applicability of the requirements to devices already in the marketplace or intended solely for export.

This rule is not intended to require manufacturers to recall any devices already in interstate commerce. Therefore, this rule does not apply to devices initially introduced or initially delivered for introduction into interstate commerce before the effective date of this regulation.

Devices intended solely for export will not be deemed misbranded for failure to comply with this regulation provided that the exporter meets the criteria of sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). Nevertheless, FDA encourages the application of a natural rubber content statement to all exported devices containing natural rubber that may contact humans.

14. A few comments suggested that devices containing less than a minimum quantity of natural rubber, the amount to be determined by the agency, be exempt from the labeling requirement. One comment suggested that devices be labeled with the extractable natural latex protein content.

The agency agrees in principle, however, insufficient information currently exists regarding the minimum

amount of extractable natural latex protein that would not elicit an allergic reaction for this option to be practicable. Evidence indicates that some persons are reactive to extremely low levels of proteins (Ref. 31). The agency is unable to determine what minimum amount of natural latex proteins fails to elicit a reaction in some individuals, and, therefore, cannot exempt devices containing less than that minimum.

15. Several comments requested clarification on the level of packaging that would require a labeling statement. Some comments requested additional flexibility in the placement of the statement so that the statement may be put on the device labeling other than the label, especially where the device label may be too small to carry such a statement. Another comment recommended that the statement be required not only on the label and in other labeling, but on the device itself if the device is dispensed in bulk, as in the case with natural rubber latex examination gloves. Other comments suggested that bulk devices either remain in the original package in order to preserve the label, or that the agency require the user facility to educate and monitor the use of bulk devices containing natural rubber. Still another comment suggested that where bulk devices are removed to a separate dispensing container, the dispensing container also be required to be labeled with a natural rubber content statement.

FDA believes that the required labeling statements may be fitted on small labels. Because of the importance of the information contained in the labeling statements for individuals sensitive to natural latex proteins, the agency will require the appropriate statements concerning the natural rubber content of the products to be prominently and legibly displayed on all device labels, and other labeling, and to appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

This means, for example, that the labeling statement for adhesive bandages that are individually wrapped and sold in a box would appear on each individually wrapped bandage, on the box, and on any individual pieces of labeling, such as an instructions for use sheet included in the box. Devices packaged and sold in bulk dispensing containers would be required to display the appropriate statement on the dispensing container, as it is the immediate device container or package.

If the packaging of a device contains natural rubber, the final regulation requires that a separate statement that specifically cautions the user that the natural rubber is contained in the packaging itself. Statements relating to the natural rubber content of the packaging do not have to appear on the same levels of labeling as the cautionary statements relating to natural rubber content in the actual product. The statements cautioning the user that the packaging contains natural rubber shall appear, instead, only on the packaging that contains the natural rubber, and the outside package, container, or wrapper. Placement of cautionary statements in these locations should warn consumers adequately of the possible risks of allergic reactions to the packaging, while avoiding the potential for confusion that the actual products contain natural rubber.

FDA believes that requiring devices to remain in their original package at the user site, requiring labeling statements on dispensers that are sold separately from the natural rubber containing devices, and requiring user facilities to provide education concerning latex products and to monitor bulk product use, is impracticable and beyond the scope of the regulation. Furthermore, because of the potential manufacturing difficulties, the agency will not require devices to be embossed, imprinted, or otherwise labeled on the individual, unwrapped device. The agency believes that the labeling requirements in this regulation will provide adequate protection to the users and patients.

16. The vast majority of comments supported the removal of the ''hypoallergenic'' claim from the labeling of medical devices that contain natural rubber. Those comments that expressed unease about the removal of the claim stated that the term does convey meaningful information to the user. These comments suggested that an alternative term be applied, or that the regulation allow device labeling to state that the device presents a reduced potential for sensitizing users to natural rubber, or that the device contains less than a specified limit of natural latex proteins or processing chemicals as established by the agency. One comment stated that, until the agency proves that the tests currently employed are insufficient to support the ''hypoallergenic'' claim, the claim should be allowed.

The agency agrees that the term ''hypoallergenic'' provides important information to the consumer who is sensitive to processing chemicals, but believes that the term ''hypoallergenic'' on products containing natural rubber will mislead consumers to conclude erroneously that the product may not cause latex protein allergic reactions.

In the past, manufacturers have labeled their products ''hypoallergenic'' on the basis of results of the modified (human) Draize test. While this test may be appropriate for detecting sensitivity to residual levels of processing chemicals, the test cannot detect the presence of natural latex proteins. Furthermore, current manufacturing processes cannot reduce the levels of natural latex proteins below that to which some individuals may react.

The agency disagrees that the ''hypoallergenic'' label should be allowed to remain on devices that contain natural rubber until the agency proves that the tests currently employed are insufficient to support the ''hypoallergenic'' claim, or that claims should be allowed regarding reduced levels of latex proteins. The agency has received reports of allergic reactions to natural rubber gloves labeled as hypoallergenic. Given that the modified (human) Draize Test is not designed to detect levels of natural latex proteins that would not induce allergic responses, and that the agency is not aware of any current manufacturing processes that are designed to remove latex proteins below a level that may cause adverse reactions, the agency believes that it has sufficient evidence that the tests currently employed do not support the claim ''hypoallergenic'' with respect to the potential for allergic reactions to natural latex proteins.

The agency does agree that alternative statements should be applied to convey information about devices with reduced residual chemical levels to consumers who are sensitive to chemicals. For this reason, the agency is developing guidance for manufacturers who want to make claims relating to latex devices that have reduced manufacturing chemical residues. FDA will announce the availability of this draft guidance document entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' in a future issue of the **Federal Register**.

17. A few comments stated that the reference to the draft guidance document entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' in the preamble to the June 24, 1996 proposed rule, upon which this final rule is based, was inappropriate because the document is still in draft form, while another comment suggested the agency reference the draft guidance document in the regulation itself.

The agency does not believe it is appropriate to incorporate a draft guidance document into a regulation. The agency, however, does believe that

it is appropriate to use the preambles of a proposed and final rule relating to latex devices to inform the public that the agency is in the process of developing a guidance document relating to claims about the sensitizing potential of manufacturing chemical residues in latex devices.

18. The vast majority of comments supported the use of a symbol to indicate the presence of natural rubber in a device. These comments stated that the symbol would promote consumer recognition and could be used on devices that have labels that are too small to fit the full text of the statement. One comment suggested that the symbol be stamped on the actual devices, especially those sold in bulk packages. Some comments stated that the symbol should supplement, not replace the text of the statement. Those comments not supporting the use of a natural rubber symbol cautioned that a symbol should not be used until it is universally accepted. Another comment suggested that the agency establish the symbol and require its use.

The agency agrees that a symbol would be useful. The agency stresses, however, that any symbol is intended to supplement, not replace the required written labeling statements, and its use would be voluntary. The agency appreciates the comments and the suggested symbol designs that were submitted, but does not believe that there is sufficient acceptance of a symbol to require the use of a symbol at this time.

19. Several comments stated that the health benefits of the labeling statement are potentially so great that the effective date of the requirement should be less than 180 days from the date of publication of this final rule. Other comments complained that a 180-day implementation period is not sufficient to change the labeling on the numerous devices affected by this rule. These comments requested at least a 12-month implementation period. One of these comments further requested that implementation be a two-stage process, and that devices containing dry natural rubber not be required to carry the labeling statement until 24 months after publication of this final rule. Another comment requested a two-stage implementation process so that devices that only indirectly contact humans would not be required to carry the labeling statement until 36 months after publication, or that such devices not be required to carry any labeling statement.

The agency agrees that the public health concerns relating to allergic responses to natural rubber are great. The agency also acknowledges, however, that at the time of the publication of this regulation, manufacturers have labeling in stock that does not have the required statements. In order to minimize the burden to manufacturers of discarding labeling that has already been printed, and to allow sufficient time to reformat labeling, the agency is providing that the effective date of this final rule is 1 year after the date of publication. This effective date will allow most manufacturers sufficient time, before the effective date of this rule, to exhaust their existing supply of labeling stock. If a manufacturer uses the existing labeling stock before the effective date of this rule, however, FDA encourages manufacturers to add the required labeling statement at that time.

The agency does not believe that a two-stage implementation process is necessary, or that a period of longer than 1 year is necessary because 1 year should be adequate time to phase in new labeling, and reformat the labeling. Furthermore, the agency believes that a longer delay in the implementation of this rule would not be in the interest of the public health. The comment suggesting that devices that only indirectly contact humans not carry any natural rubber labeling statement is addressed in comment 4 of this document.

20. One comment suggested that manufacturers, distributors, and user facilities all be responsible for following the labeling requirements.

The agency agrees with the underlying concern that the labeling statement remain on devices. It is only necessary, however, to require manufacturers to properly label their products to ensure that consumers receive appropriate information concerning natural rubber products. Distributors and user facilities may not alter the device labeling. Any such alteration may be grounds for a charge of misbranding a device under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 352(a), (c), and (f)).

21. A few comments complained that the rule could be misinterpreted to require labeling on all devices containing any natural rubber whatsoever. Others stated that the requirement would have a major impact on multinational companies, costing at least $15,000 per device for labeling. Another comment stated that the agency underestimated the impact of the rule, as each manufacturer will need to draft, review, and relabel primary and secondary packages of hundreds, if not thousands of devices.

The agency has clarified the scope of this regulation in order to minimize the possibility of misinterpretation. Under final § 801.437(b), an appropriate labeling statement is required on medical devices that contain natural rubber latex or dry natural rubber that contacts humans. The agency does not believe that this rule would require relabeling for hundreds or thousands of devices. In fact, the agency has only identified approximately 70 generic types of medical devices including combination products that are subject to this rule.

Furthermore, FDA does not agree that this rule will have a major impact on multinational companies because it would cost at least $15,000 per device for labeling. FDA estimates that the cost to revise the labeling would be between $1,000 and $2,000 for each type of device that is relabeled. Moreover, the cost of implementing this regulation is further minimized because the 1-year effective date of this regulation should allow most manufacturers to exhaust their current labeling stock prior to using the labeling that is required under this regulation.

IV. Paperwork Reduction Act of 1995

The warning statements required by this regulation are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public * * *'' (5 CFR 1320.3(c)(2)). Accordingly, FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) 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.

VI. 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), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–4). 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.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule primarily requires a labeling change which would not have a significant economic impact on small entities. Although this rule will require a labeling change on a substantial number of medical devices, manufacturers will be allowed up to 1 year after the effective date of this regulation to exhaust their existing supply of labeling, therefore, most manufacturers would exhaust their existing supply of labels. Moreover, the cost of reformatting the labeling, which is $1,000 to $2,000 for each different kind of device, is not significant. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.437 is added to subpart H to read as follows:

§ 801.437 User labeling for devices that contain natural rubber.

(a) Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and protect the public health.

(b) This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term ''natural

rubber'' includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

(1) The term ''natural rubber latex'' means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating.

(2) The term ''dry natural rubber'' means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping.

(3) The term ''contacts humans'' means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient.

(c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)).

(d) Devices containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling:

''This Product Contains Dry Natural Rubber.''

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''The Packaging of This Product Contains Dry Natural Rubber.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term ''hypoallergenic'' on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with § 10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

Dated: September 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25728 Filed 9–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2610]

Bureau of Consular Affairs; Visas: Passports and Visas Not Required for Certain Nonimmigrants

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Interim rule with request for comments.

SUMMARY: Section 217 of the Immigration and Nationality Act (INA), as amended, extends the Visa Waiver Pilot Program (VWPP) to nationals of all countries that qualify under the provisions of the Pilot Program and which are designated by the Secretary of State and the Attorney General as countries whose nationals benefit from the waiver of the nonimmigrant B–1/B–2 visa requirement. This interim rule eliminates probationary entry status in the pilot program, designates Ireland (the only country formerly designated as a participating country with probationary status) as a permanent participating country and extends the VWPP to Slovenia.

DATES: This interim rule is effective September 30, 1997. Written comments are invited and must be received on or before October 30, 1997.

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Room L–603C, Department of State, Washington, D.C. 20520–0106.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Department of State, Washington, D.C. 20522–0113 (202) 663–1203.

SUPPLEMENTARY INFORMATION: This interim rule amends Part 41, Title 22 of the Code of Federal Regulations concerning visas for nonimmigrants pursuant to section 217 of the Immigration and Nationality Act, 8 U.S.C. 1187, as amended by Pub. L. 103–415, (108 Stat. 4299, October 25,1994), Pub. L. 103–416, (108 Stat. 4305, October 25, 1994), and Pub. L. 104–208, (110 Stat. 3009–702, September 30, 1996).

Pub. L. 99–603

Section 313 of the Immigration Reform and Control Act of 1986 (IRCA), Pub. L. 99–603, amended the INA by adding a new section 217 (8 U.S.C. 1187). Section 217 provides for a nonimmigrant visa waiver pilot program (VWPP) which waives the nonimmigrant visa requirement for the admission of certain aliens into the United States for a period not to exceed ninety days. This original provision authorized the participation of eight countries in the VWPP to be designated by the Secretary of State and the Attorney General, acting jointly from among countries meeting specific criteria. These original qualifying countries included: France; the Federal