natural rubber, such information is likely to be presented in a variety of ways that may confuse consumers and limit the effectiveness of the natural rubber statement. FDA believes that the provision of consistent, accurate information to consumers is critical. FDA believes that this regulation, which provides accurate, consistent information in a standardized manner, will assure that the safety information is communicated effectively to the public.

C. Implementation Periods

FDA considered various implementation periods for the effective date after the issuance of the final rule. The June 24, 1996, proposed rule proposed an effective date 6 months after the publication of the final rule. The final rule has reduced the impact on small businesses by extending the effective date to 1 year after issuance of the final rule for all products, except those containing natural rubber latex solely in cold-seal type packaging. For those products the agency is providing, for the reasons stated previously, an additional 270 days to comply with the rule.

Based on the ERG report figures, the total industry cost of compliance for this rule with a 1-year implementation period is $64.1 million. This figure may be somewhat higher than actual costs because of the extension for compliance granted to cold seal packaged products, however FDA did not reduce cost estimates related to this variable. The total annualized costs are calculated at $9.1 million per year. The costs for a 6-month effective date are 26 percent greater than a 1-year effective date. Allowing a 24-month implementation date would reduce costs by 40 percent.

FDA rejected the 6-month implementation period and extended the implementation period to 1 year to allow manufacturers of products containing natural rubber latex, including small businesses, to reduce costs by depleting existing inventories and coordinating this labeling change with other planned labeling changes. Although costs could further be reduced by allowing a 24-month implementation period, FDA believes that the public need for this information about devices that pose serious risks justifies rejecting this alternative.

D. Exempting Small Businesses

FDA has considered the option of exempting small businesses from the final regulation. The ERG report estimates that approximately 83 percent of the manufacturers of natural rubber latex products are small businesses. FDA believes that given that the large majority of manufacturers of products containing natural rubber latex are small businesses, and given the risks associated with these devices, exempting small businesses from this regulation would result in a significant decrease of consumer protection. Accordingly, FDA does not believe that small businesses should be exempt from this regulation.

E. Allowance of Supplementary Labeling

FDA could have chosen a regulatory alternative that would require that all labeling be directly printed on the existing packaging and labeling. Such a regulatory provision would decrease the possibility that the required statement would become dislodged during distribution. Instead, the final rule allows the use of supplementary labeling (stickers) to provide the required labeling information. As noted in the ERG report, this will allow a number of firms, including small businesses, to reduce costs by avoiding extensive repackaging of existing product inventory that will not be sold prior to the end of the regulatory implementation period. FDA decided to include this option in the final rule.

F. Requiring a Labeling Statement on Only One Level of Labeling

Under the provisions of the final rule, FDA estimates that most devices covered under the final rule will bear the required natural rubber statement on two or three levels of labeling. FDA considered requiring labeling statements on only one level of labeling. This alternative was rejected because of the importance of the information contained in the required labeling statements. Users may not have the necessary opportunity to read the statement if it is included only on some levels of labeling. For some products, especially those with multiple users, some labeling may be discarded prior to use by subsequent consumers. The inclusion of the statement on each level of labeling increases the likelihood that consumers will be aware of the risks posed by the natural rubber in the product.

V. References

The following references have 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. Kibby, T., and M. Akl, ''Prevalence of Latex Sensitization in a Hospital Employee Population,'' *Annals of Allergy, Asthma and Immunology*, 78:41–44, 1997.

2. Kaczmarek, R. G., B. G. Silverman, T. P. Gross, et al., ''Prevalence of Latex-specific IgE Antibodies in Hospital Personnel,'' *Annals of Allergy, Asthma and Immunology*, 76:51–56, 1996.

3. Arellano, R., J. Bradley, and G. Sussman, ''Prevalence of Latex Sensitization Among Hospital Employees Occupationally Exposed to Latex Gloves,'' *Anesthesiology*, 77:905–908, 1992.

4. Lagier, F., D. Vervloet, I. Lhernet, et al., ''Prevalence of Latex Allergy in Operating Room Nurses,'' *Journal of Allergy and Clinical Immunology*, 90:319–322, 1992.

5. Yassin, M., M. Lierl, T. Fisher, et al., ''Latex Allergy in Hospital Employees,'' *Annals of Allergy*, 72:245–249, 1994.

6. June 5, 1998, HIMA citizen petition requesting a stay of the implementation of the final rule as it pertains to packaging.

7. June 19, 1998, FDA response to HIMA citizen petition requesting stay of the implementation of the final rule as it pertains to packaging.

VI. Public Outreach

FDA has conducted extensive public outreach relating to the final rule to small businesses. Interactions with the public on issues relating to this rule are discussed in detail in the amended economic analysis statement published in the **Federal Register** of June 1, 1998 (63 FR 29552, at 29553 and 29554).

Dated: August 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23304 Filed 8–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 96N–0119]

Natural Rubber-Containing Medical Devices; User Labeling; Cold Seal Adhesives Partial Stay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The final rule for user labeling requirements for natural rubber-containing medical devices, 21 CFR 801.437, was published on September 30, 1997, and becomes effective on September 30, 1998. The Food and Drug Administration (FDA) is adding a note to that rule to stay, for 270 days from the effective date, paragraphs (f) and (g) as those final rule requirements relate to device packaging that uses ''cold seal'' adhesives. Labeling changes required by other paragraphs of this final rule must be incorporated in the labeling of devices

distributed after September 30, 1998, even if the devices are packaged in ''cold seal'' packages. Device packaging that uses natural rubber only on adhesives contained in the flaps of device packaging is not considered subject to the rule. Manufacturers of devices packaged with ''cold seal'' adhesives may, if necessary, submit a petition for an extension of the 270-day stay.

DATES: Effective September 30, 1998, until June 27, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4616.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA issued a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. The rule becomes effective on September 30, 1998. On June 5, 1998, the Health Industry Manufacturers Association (HIMA) filed a citizen petition requesting FDA to stay implementation of the final rule as it pertains to adhesives used in packaging, and packaging in general, of medical devices. On June 19, 1998, FDA denied the HIMA petition with respect to packaging in general but stated FDA would grant a stay of the effective date of paragraphs (f) and (g) of § 801.437 for 270 days from the effective date of the final rule as it pertains to device packaging that uses ''cold seal'' adhesives. Labeling changes required by other paragraphs of the final rule, such as elimination of the word ''hypoallergenic'' and inclusion of the latex content statement for devices that have natural rubber in places other than the packaging must be incorporated into the labeling of devices distributed after September 30, 1998, even if those devices are packaged in ''cold seal'' packages. The agency's response to HIMA's petition also clarified that FDA does not consider device packaging that uses natural rubber only on adhesives contained in the flaps of device packaging to be subject to the rule because such adhesives are not intended and are not likely to contact humans. The petition from HIMA and the agency's response are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. The agency's response is also available on the FDA home page at http://www.fda.gov/cdrh.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner finds that this stay is in the public interest.

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: 21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374.

2. Section 801.437 is amended by adding the following note to the end of the section:

§ 801.437 User labeling for devices that contain natural rubber.

* * * * *

Note to § 801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses ''cold seal'' adhesives.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23303 Filed 8–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07–98–023]

RIN 2115–AE84

Regulated Navigation Area; San Juan Harbor, San Juan, PR

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary regulated navigation area in San Juan Harbor in the vicinity of La Puntilla in San Juan, PR. This regulated navigation area is needed to protect personnel, vessels, and equipment during the construction of piers at Coast Guard Base San Juan from the hazards created by the wakes of passing vessel traffic. By establishing this temporary regulation, the Coast Guard expects to reduce the risk of personnel injury and property damage.

DATES: This rule is effective from August 10, 1998, through August 10, 1999.

FOR FURTHER INFORMATION CONTACT: LT D.R. XIRAU, Assistant Chief Port Operations Department, USCG Marine Safety Office San Juan at (787) 729–6800, ext 320.

SUPPLEMENTARY INFORMATION:

Background and Purpose

These regulations create a temporary regulated navigation area requiring all vessels to operate at no-wake speed in the vicinity of Coast Guard Base San Juan. These regulations are necessary to provide for the safety of personnel, vessels, and equipment during the construction of several piers at Coast Guard Base San Juan. Coast Guard Base San Juan is located at La Puntilla in Old San Juan, at a junction of major channels in the San Juan Harbor. The Coast Guard believes that a significant risk exists under current conditions because wakes cause damage to vessels and the piers, and create major safety hazards to personnel working on the piers and on board moored vessels.

Heavy wakes can cause damage to property while undergoing construction at Coast Guard Base San Juan. Vessel hulls, cleats, stanchions, and gangways have been bent or parted in the past. In addition, electrical shore ties and fueling hoses have been pulled loose, creating very hazardous situations. By establishing a temporary no-wake speed zone in the vicinity of La Puntilla, the risks to personnel and property inherent to wakes will be minimized during the construction.

In accordance with 5 U.S.C. 533, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical. Construction is scheduled to begin in a few days and there was not sufficient time to publish proposed rules prior to the construction event nor to provide for a delayed effective date.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040;