that will be announced in the **Federal Register**.

(d) *Carrier responsibility for comparing information collected with travel document.* The carrier collecting the information described in paragraph (c)(2) of this section is responsible for comparing this information with the related travel document under paragraph (c)(3) of this section, in order to ensure that the information is correct, that the document appears to be valid for travel to the United States, and that the passenger or crew member, as applicable, is the person to whom the travel document was issued.

(e) *Sharing of manifest information with other Federal agencies.* Information contained in passenger and crew manifests for flights subject to paragraph (a) of this section (49 U.S.C. 44909(c)(1)) that is received by Customs electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security (49 U.S.C. 44909(c)(5)).

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding the following in appropriate numerical sequence according to the section number under the columns indicated:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control no.
*	* * * *	*
§ 122.49a	Passenger and crew manifests.	1515–0232
*	* * * *	*

Approved: December 21, 2001.

Robert C. Bonner,

Commissioner of Customs.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–32034 Filed 12–28–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N–0038]

RIN 0910–AA01

Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay.

SUMMARY: The Food and Drug Administration (FDA) is staying the final monograph for over-the-counter (OTC) sunscreen drug products that published in the **Federal Register** of May 21, 1999 (64 FR 27666). The final monograph established conditions under which OTC sunscreen drug products are generally recognized as safe and effective and not misbranded. This stay of effective date applies to all OTC sunscreen drug products that would be regulated under part 352 (21 CFR part 352). This action does not stay the effective date for products that would be regulated under parts 310 and 700 (21 CFR parts 310 and 700). This action is being taken because the agency will be amending part 352 to address formulation, labeling, and testing requirements for both ultraviolet A (UVA) radiation protection and ultraviolet B (UVB) radiation protection. This action is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective January 30, 2002. Part 352, added at 64 FR 27666 at 27687, is stayed until further notice. Written or electronic comments by April 1, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 21, 1999, FDA published a final rule in the form of a final monograph for OTC sunscreen drug products in part 352. The monograph included 16 active ingredients, required labeling for products that contain one or more of these active ingredients, a standardized test for measuring sun protection factor (SPF) values, and standard methods for measuring the water resistant properties of sunscreens. The labeling and test methods covered products intended to provide UVB radiation protection. The monograph did not, however, address active ingredients, labeling, and test methods for products intended to provide UVA protection. The final rule also included related nonmonograph conditions in § 310.545(a)(29) (21 CFR 310.545(a)(29)) and new § 700.35 (21 CFR 700.35), which addressed labeling for cosmetic products that contain sunscreen active ingredients for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). The agency set a 2-year effective date (May 21, 2001) for part 352 and for §§ 310.545(a)(29) and 700.35.

In the **Federal Register** of June 8, 2000 (65 FR 36319), the agency extended the effective date for all OTC sunscreen drug and cosmetic products that would be regulated under parts 310, 352, and 700 to December 31, 2002. The agency stated that this extension would be in the public interest as the agency developed a comprehensive sunscreen final monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352. The agency stated in this notice that it intended to move forward and publish a proposed rule for a comprehensive final monograph, receive comments on that proposal, and issue a final rule by December 31, 2001. That final rule would then have a 1-year effective date of December 31, 2002.

II. Stay of Part 352

The June 8, 2000, extension of effective date also included a reopening of the administrative record to allow for comment on specific information the agency requested in that document. The comment period closed on September 6, 2000. Since that time, the agency has been developing a proposed amendment to part 352 that addresses both UVB and UVA radiation protection.

The agency expects to publish the proposal to amend part 352 next year. Following that publication, there will be a comment period and then the agency will prepare an amended final monograph for publication in a future issue of the **Federal Register**. Because the agency has not yet published the proposed amendment to part 352, it is not possible for manufacturers of OTC sunscreen drug products to relabel and

test their products in accord with an amended final monograph by the current effective date of December 31, 2002.

Accordingly, the agency is staying part 352 until further notice is provided in a future issue of the **Federal Register**. The agency will propose a new effective date for part 352 within the proposed amendment. The agency anticipates that this new effective date will not be before January 1, 2005.

This stay of effective date does not apply to parts 310 or 700, because the amendment of the monograph in part 352 has no effect on the requirements in these parts. The agency has already extended the effective dates for parts 310 and 700 to December 31, 2002, and finds there is no reason to further extend that date.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. (553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and (d)(3) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency is staying part 352 because the agency has determined that it is not possible for manufacturers of OTC sunscreen drug products to relabel and test their products in accord with an amended final monograph by the current effective date of December 31, 2002. The agency intends to publish a proposal to amend part 352 next year in order to develop a comprehensive sunscreen monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection. This amendment will propose a new effective date for part 352. Thus, there will be an opportunity for public comment on the new effective date within the proposed amendment to part 352. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this partial stay should be modified or revoked.

III. Analysis of Impacts

The economic impact of the final monograph was discussed in the final rule (64 FR 27666 at 27683). The economic impact of the extension of the effective date of the monograph until December 31, 2002, was discussed in the final rule extending that date (65 FR 36319 at 36323). This stay of the effective date provides additional time for companies to relabel and retest products, eliminates a second relabeling of sunscreen drug products when UVA labeling is included in the monograph, and reduces label obsolescence, as there will be additional time to use up more existing labeling. Thus, staying the effective date will significantly reduce the economic impact on industry.

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 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the regulatory philosophy and principles set out in the Executive order and in these two statutes. 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. FDA has determined that the final rule does not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

The purpose of this final rule is to stay the effective date of the final monograph for OTC sunscreen drug products in part 352. This will provide additional time for manufacturers to relabel and retest products and to use up existing product labeling. The agency encourages manufacturers who use up their existing product labeling before the amended final monograph is issued to prepare new labeling in accord with the existing final monograph in part 352 in the format set forth in § 201.66 (21 CFR 201.66). Accordingly, the agency certifies that this 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.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this rule by April 1, 2002. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This final rule (partial stay) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under

authority delegated to the Commissioner of Food and Drugs.

Dated: December 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–32086 Filed 12–28–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–01–207]

RIN 2115–AA97

Security Zone: Seabrook Nuclear Power Plant, Seabrook, New Hampshire

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone around the Seabrook Nuclear Power Plant in Seabrook, New Hampshire. The security zone will close off public access to all land and waters within 250 yards of the waterside property boundary of Seabrook Nuclear Power Plant. This action is necessary to ensure public safety and prevent sabotage or terrorist acts. Entry into this security zone is prohibited unless authorized by the Captain of the Port, Portland, Maine.

DATES: This rule is effective from December 7, 2001 until June 15, 2002.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD01–01–207 and are available for inspection or copying at Marine Safety Office Portland, Maine, 103 Commercial Street, Portland, Maine between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) W. W. Gough, Port Operations Department, Captain of the Port, Portland, Maine at (207) 780–3251.

SUPPLEMENTARY INFORMATION:

Regulatory History

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. On September 11, 2001, two commercial aircraft were hijacked from Logan Airport in Boston, Massachusetts and flown into the World Trade Center in New York, New York inflicting catastrophic human casualties and property damage. National security and intelligence officials warn that future terrorist attacks against civilian targets may be anticipated. The Seabrook Nuclear Power Plant is open to possible attack from waters adjacent to nearby Hampton Harbor. Due to the potential catastrophic effect an exposure of radiation from the nuclear processes at the plant would have on the surrounding area, this rulemaking is urgently required to prevent potential future terrorist strikes against the Seabrook Nuclear Power Plant. The delay inherent in the NPRM process is contrary to the public interest insofar as it may render people and facilities within and adjacent to the Seabrook Nuclear Power Plant property vulnerable to subversive activity, sabotage or terrorist attack.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The measures implemented in this rule are intended to prevent possible terrorist attacks against the Seabrook Nuclear Power Plant and are needed to protect the facility, persons at the facility, the public and the surrounding community from potential sabotage or other subversive activity, sabotage and terrorist attacks, either from the water or by access to the facility by utilizing public trust lands between the low water and high water tide lines. Immediate action is required to accomplish these objectives. Any delay in the effective date of this rule is impracticable and contrary to the public interest.

This zone should have minimal impact on the users of Hampton Harbor, New Hampshire and the surrounding waters as vessels are able to pass safely outside the zone. Public notifications will be made to the maritime community via local notice to mariners and signs posted to inform the public of the boundaries of the zone.

Background and Purpose

In light of terrorist attacks on New York City and Washington D.C. on September 11, 2001 a security zone is being established to safeguard the Seabrook Nuclear Power Plant, persons at the facility, the public and surrounding communities from sabotage or other subversive acts, accidents, or other events of a similar nature. The Seabrook Nuclear Power Plant presents a possible target of terrorist attack due to the catastrophic impact a release of nuclear radiation would have on the surrounding area. This security zone prohibits entry into or movement within the specified areas.

This rulemaking establishes a security zone in all land and waters within 250 yards of the waterside property boundary of Seabrook Nuclear Power Plant in Seabrook, New Hampshire bounded by a line beginning at position 42°53′58″ N, 070°51′06″ W, then running along the Seabrook Nuclear Power Plant property boundaries, ending at position 42°53′46″ N, 070°51′06″ W. The area along the Plant property boundaries is an area delineated by a fence, and runs east around the easternmost point of the property boundaries of Seabrook Nuclear Power Plant, then turns west to the point of termination. This security zone also closes all land within the zone to prevent access along areas traditionally reserved for public use between the mean low water tide line and the mean high water tide line. This rulemaking is necessary to provide complete protection of the waterfront areas of the Seabrook Nuclear Power Plant.

No person or vessel may enter or remain in the prescribed security zone at any time without the permission of the Captain of the Port. Each person or vessel in a security zone shall obey any direction or order of the Captain of the Port. The Captain of the Port may take possession and control of any vessel in a security zone and/or remove any person, vessel, article or thing from a security zone. No person may board, take or place any article or thing on board any vessel or waterfront facility in a security zone without permission of the Captain of the Port.

Regulatory Evaluation

This temporary final 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. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

The effect of this regulation will not be significant for several reasons: The protected area is not regularly navigated; there is ample room for vessels to navigate around the security zone; notifications will be made to the local maritime community; and signs