

**ADDRESS:** Comments may be submitted to and inspected at the Regulations and Disclosure Law Branch, U.S. Customs Service, Room 2119, 1301 Constitution Ave., NW., Washington, DC 20229. All comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), between 9:00 a.m. and 4:30 p.m. on normal business days, at the address above.

**FOR FURTHER INFORMATION CONTACT:** Russell Berger, Regulations and Disclosure Law Branch, (202)-566-8237.  
**SUPPLEMENTARY INFORMATION:**

### Background

A document published in the Federal Register on October 4, 1989 (54 FR 40882), proposed, in significant part, to amend the Customs Regulations to enable persons seeking protection from infringing semiconductor chip products (mask works) to obtain the assistance of Customs in preventing pirated chips from being imported into the U.S. This would give rise to a process of Customs recordation of mask works similar to that for copyrights in part 133, Customs Regulations (19 CFR part 133).

This proposed remedy would be in addition to, and not in lieu of, the mask work owner's other rights and remedies, such as the right to attempt to secure an injunction against importation from a district court or an exclusion order from the U.S. International Trade Commission (USITC). These latter protections, which are currently afforded mask work owners in § 12.39(d), Customs Regulations (19 CFR 12.39(d)), would thus be expanded upon and included in part 133. Also, for purposes of administrative convenience and consolidation, § 12.39 covering "patent import surveys", would be transferred into part 133.

Comments on the proposed rulemaking were to have been received on or before December 4, 1989. Customs has, however, received a number of requests to extend the period of time for comments, the requesters stating that they need additional time in order to give the proposed careful and complete review. Customs believes, under the circumstances, that these requests have merit. Accordingly, the period of time for the submission of comments is being extended as indicated.

Furthermore, the information collection aspects of the proposal as set forth in the document under "PAPERWORK REDUCTION ACT" omitted reference to certain regulations

which also involve information collection.

### Correction

On page 40883 of the document, the first sentence of the second paragraph under "Paperwork Reduction Act" should read as follows:

### Paperwork Reduction Act

The collection of information in this regulation is in §§ 133.52, 133.53, 133.55, 133.56 and 133.81. \* \* \*

Dated: January 17, 1990.  
Carol Hallett,  
Commissioner of Customs.  
[FR Doc. 90-1551 Filed 1-23-90; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 341

[Docket No. 76 N-052 G]

RIN 0905-AA06

### Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Reopening of Record for Receipt of Comments Regarding the Marketing Status of Combination Drug Products Containing Promethazine Hydrochloride; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to May 29, 1990, the period for comments on the reopening of the administrative record for the proposed rulemaking for over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) combination drug products to accept additional comments and data concerning combination drug products containing promethazine hydrochloride. This action responds to a request to extend the comment period for an additional 120 days to allow sufficient time to submit additional information pertinent to the marketing status of combination drug products containing promethazine hydrochloride.

**DATE:** Written comments by May 29, 1990.

**ADDRESS:** Written comments to the Dockets Management Branch (HFA-

305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of November 28, 1989 (54 FR 48914), FDA issued a notice reopening the administrative record for the rulemaking on OTC cough-cold combination drug products to allow for additional comments on the agency's decision not to allow promethazine-containing combination drug products for use in treating the symptoms of the common cold to be marketed OTC at this time, which was published in the Federal Register of September 5, 1989 (54 FR 38762). A significant part of the agency's decision not to allow the OTC marketing of these promethazine-containing drug products was based on the recommendations of the Pulmonary-Allergy Drugs Advisory Committee made at its July 31, 1989, meeting. As noted in the November 28, 1989, notice, the administrative record for the proposed rule on OTC cough-cold combination drug products had several closing dates: August 14, 1989, for the submission of new data and October 12, 1989, for the submission of comments on the new data submitted. Because the advisory committee's recommendations were not made until July 31, 1989, and the agency's decision was not announced until September 5, 1989, the agency reopened the administrative record to allow additional time for further public comment and to accept any additional available data relating to the marketing status of combination cough-cold drug products containing promethazine hydrochloride. Interested persons were given until January 29, 1990, to submit comments and data.

In response to the notice reopening the administrative record, Wyeth-Ayerst Laboratories requested a 120-day extension of the comment period to allow sufficient time for the submission of additional information which the company believes is essential for FDA to make a proper and informed decision regarding the ultimate marketing status of combination drug products containing promethazine hydrochloride. The company concluded that the 60-day comment period would not allow sufficient time for the collection, preparation, and submission of appropriate additional information that

is pertinent to the rulemaking proceeding.

FDA has carefully considered the request. The agency believes that, because of the number of issues raised at the advisory committee's meeting, allowing additional time for the submission of comments and additional data addressing these issues would enable the agency to more fully evaluate and review all information pertaining to the marketing status of cough-cold combination drug products containing promethazine hydrochloride and would be in the public interest. Thus, the agency considers an extension of the comment period for 120 days for information concerning this subject only to be appropriate. The non-OTC marketing status of promethazine-containing combination drug products announced on September 5, 1989, is not affected by this extension of time. Further, this extension will not delay completion of the rulemaking for OTC cough-cold combination drug products.

Interested persons may, on or before May 29, 1990, submit to the Dockets Management Branch (address above) written comments on the OTC marketing of promethazine-containing cough-cold combination drug products. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 16, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 89-1567 Filed 1-23-90; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### 30 CFR Part 256

RIN 1010-AB38

#### Outer Continental Shelf Minerals and Rights-of-Way Management; Surety Bond Coverage

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the provisions of part 256 of title 30 of the Code of Federal Regulations (CFR) to increase the amount of surety bond coverage required of lessees, operators, or assignees prior to the

commencement of exploration and prior to the commencement of development and to require that bonds be issued by a surety that is certified by the U.S. Department of the Treasury. The proposed rule would also identify with greater specificity the parties responsible for furnishing the required bond coverage prior to the Minerals Management Service's (MMS) approval of a lease transfer and assignment. These revisions are being proposed because the current level of bond coverage was established about 20 years ago and is clearly insufficient to cover increased costs of compliance with the conditions and terms of a lease in the event of a significant default.

**DATE:** Comments must be hand delivered or postmarked no later than March 28, 1990.

**ADDRESS:** Written comments must be mailed or hand delivered to the Department of the Interior; Minerals Management Service; 381 Elden Street; Mail Stop 646; Herndon, Virginia 22070-4817; Attention: Gerald D. Rhodes.

**FOR FURTHER INFORMATION CONTACT:** Gerald D. Rhodes, Telephone (703) 787-1600.

**SUPPLEMENTARY INFORMATION:** In proposing these amendments to the regulations governing the issuance and maintenance of OCS oil and gas leases, MMS is fulfilling its obligations under the OCS Lands Act (OCSLA) to prescribe such rules and regulations as may be necessary to carry out the provisions of that Act (43 U.S.C. 1334). Accordingly, lessees are required to furnish a corporate surety bond "conditioned on compliance with all the terms and conditions of the lease." (30 CFR 256.58). Section 8 of OCS oil and gas leases provides that:

The lessee shall maintain at all times the bond(s) required by regulations prior to the issuance of the lease and shall furnish such additional security as may be required by the lessor, if after operations have begun, the lessor deems such additional security to be necessary.

Among the more significant regulatory requirements and conditions of OCS oil and gas leases in terms of financial obligations are those governing royalty payments and well abandonment and site clearance provisions requiring clearance of the lease premises within 1 year after the expiration of the lease. A National Academy of Sciences study commissioned by MMS in 1985 estimates that removal costs in the Gulf of Mexico of smaller, comparatively light-weight structures in relatively shallow water could range up to \$400,000. These costs increase with water depth and the size and complexity

of the structure. Removal and site clearance costs are estimated to be at least \$15 million for individual deepwater structures. The amount of surety bond coverage (\$50,000 per lease or \$300,000 per OCS area) required by current regulations was established about 20 years ago and is clearly insufficient to cover the costs to the lessor in the event of a default by a lessee, particularly a default with respect to compliance with well abandonment, platform removal, and site clearance requirements.

In light of the amount of these potential liabilities for abandonment and lease cleanup costs, and the costs of other operations undertaken in the exploration, development, and production of OCS oil and gas leases, MMS believes that an increase in the amount of the surety bonds required of OCS oil and gas lessees is in order. The proposed rule would remedy this situation by adding two new tiers to current bonding requirements which would become applicable when a lessee submits an Exploration Plan for MMS approval and when a lessee submits a Development and Production Plan or a Development Operations Coordination Document submitted prior to or in association with an Exploration Plan unless the lessee furnishes and maintains a \$1,000,000 areawide bond. A \$500,000 lease bond would have to be submitted prior to or in association with a Development and Production Plan or a Development Operations Coordination Document, unless the lessee furnishes and maintains a \$3,000,000 areawide bond. These increased amounts for bond coverage would apply to all leases as Exploration Plans and Development and Production Plans or Development Operations Coordination Documents are submitted for review and approval.

Other changes being proposed are intended to assure that in cases where there is an assignment by lessees of lease operating rights or record title interests, procedures are established to assure that adequate surety bond coverage is furnished and maintained by the assignee.

The MMS also is considering additional measures to provide assurance of payment of costs associated with well abandonment and site clearance. Comments and recommendations are requested on the requirement that sureties be certified by the U.S. Treasury as well as the following:

Further rulemaking to replace the provisions of proposed § 256.61(b) with a provision for a variable bond that would increase as a percent of the total investment