2. TVA 60th Anniversary.

New Business

C—Energy

C1. Contract with International Combustion Limited for Gallatin Fossil Plant Low NOx Burner Assemblies.

C2. Arrangements with Oklahoma Gas and Electric Company (OG&E) Providing for TVA Purchases from OG&E.

E—Real Property Transactions

E1. Sale of Permanent Easement Affecting Approximately 0.06 Acre of Land to the West Lauderdale Water and Fire Protection Authority for a Water Tank Site—State Line, Alabama, Repeater Station Property—Tract No. XWJRS–1WS—Lauderdale County, Alabama.

E2. Public Auction Sale Affecting Approximately 10.5 Acres of Lane—Former Marshall and Henderson Manufacturing, Inc., Kiln Property— Tract No. XWEMP–1—Weir, Choctaw County, Mississippi.

E3. Abandonment of Transmission Line Easements Affecting Approximately 3.5 Acres of Land to the Underlying Landowner, Adam D. Hamilton—TVA's Arlington-Jefferson City Right-Of-Way—Tract Nos. HQJC–1 and HQJCR–2—Jefferson County, Tennessee.

E4. Abandonment of Easement Rights Affecting Approximately 0.05 Acre of Land—Elgin and Jean C. Smith—Tract No. XCR–30—Hamilton County, Tennessee, Chickamauga Lake.

E5. Abandonment of Easement Rights Affecting Approximately 0.01 Acre of Land—Alex Biles—Tract No. BR–216F—Washington County, Tennessee, Boone Lake.

E6. Abandonment of TVA Easement Rights Affecting Approximately 16.5 Acres of Land—McKinnon Bridge Company, Inc.—Tract Nos. WBR–1608F, –1609F, and –1610F—Loudon County, Tennessee, Watts Bar Lake.

E7. Grant of Permanent Easement Affecting 12.04 Acres of Land for a Highway Right-Of-Way—Tennessee Department of Transportation—Tract No. XTGR–159H—Marion County, Tennessee, Guntersville Lake.

E8. Sale of Noncommercial, Nonexclusive Permanent Easement Affecting 0.16 Acre of Land for Construction and Maintenance of Recreational Water Use Facilities—Alan Kuntz—Tract No. XTELR–113RE—Loudon County, Tennessee, Tellico Lake.

F—Unclassified

F1. License to Science Applications International Corporation to Use and Distribute the On-Line Diagnostic Monitoring System Software and Information.

F2. Filing of Condemnation Case.

INFORMATION ITEMS:

1. Realignment of Hydro Benefit to Residential Consumers.

2. Jobs and Education Bill Credit Program.

CONTACT PERSON FOR MORE INFORMATION: Alan Carmichael, Vice President, Government Relations, or a member of his staff can respond to requests for information about this meeting. Call (615) 632–6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 479–4412.

Dated: May 5, 1993.

Edward S. Christenbury,

General Counsel and Secretary.

[FR Doc. 93–11041 Filed 5–6–93; 10:01 am]

BILLING CODE 8120–08–M

Corrections

Federal Register
Vol. 58, No. 88
Monday, May 10, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2389-012-Maine]

Edwards Manufacturing Co.; Intent to Prepare an Environmental Impact Statement

Correction

In notice document 93-9467 beginning on page 21715 in the issue of Friday, April 23, 1993, in the third column, under the subject heading, "April 29, 1993" should read "April 19, 1993".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Services

Tetanus/Diptheria and Tetanus Vaccine Information Materials

Correction

In notice document 93-7767 beginning on page 17603 in the issue of Monday, April 5, 1993, make the following correction:

On page 17605, before the file line at the bottom of the page, insert "Td-Int. April 5, 1993."

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID-020-4210-05; I-29559]

Twin Falls County, ID, Hub Butte Landfill Proposal; Intent To Prepare an Environmental Impact Statement/Plan Amendment

Correction

In notice document 93-5683 beginning on page 13640, in the issue of Friday, March 12, 1993, make the following correction:

1. On page 13641, in the first column, in land description T. 11 S., R. 17 E., in Sec. 32, in the first line insert a comma after "W½", and the second line should be removed.

BILLING CODE 1505-01-D

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AG17

Dependency and Indemnity Compensation Reform Act of 1992

Correction

In rule document 93-9736 beginning on page 25561 in the issue of Tuesday, April 27, 1993, make the following correction:

§ 3.5 [Corrected]

On page 25561, in the third column, in § 3.5(e)(1), in the fifth line, insert "the" after "be".

BILLING CODE 1505-01-D

federal register

Monday
May 10, 1993

Part II

Department of Transportation

Coast Guard

33 CFR Part 89
Inland Navigation Rules, Gulf Intracoastal-Coastal Waterway; Final Rule

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 89

[CGD 91-050]

RIN 2115-AE09

Waters on Which Certain Inland Navigation Rules Apply

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending the regulations implementing the Inland Navigation Rules by defining certain portions of the Gulf Intracoastal-Coastal Waterway as waters "specified by the Secretary". This will allow towboat operators on designated portions of the Gulf Intracoastal Waterway to use a rule designed for certain rivers and narrow waterways, exempting them from using white masthead lights, thus improving navigation safety.

EFFECTIVE DATE: July 9, 1993.

ADDRESSES: Unless otherwise indicated, documents referenced in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G-LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street, SW., room 3406, Washington, DC 20593-0001 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Epstein, Navigation Rules and Information Branch, Office of Navigation Safety and Waterway Services, (202) 267-0352 or (202) 267-0357.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Jonathan Epstein, Project Manager, Office of Navigation Safety and Waterway Services, and Helen Boutrous, Project Counsel, Office of Chief Counsel.

Regulatory History

On September 18, 1992, the Coast Guard published a notice of proposed rulemaking entitled "Waters on Which Certain Inland Navigation Rules Apply" in the **Federal Register** (57 FR 43169). The Coast Guard received four letters commenting on the proposal. A public hearing was not requested and one was not held.

Background and Purpose

Under the Inland Navigation Rules Act of 1980 (Pub. L. 96-591, 33 U.S.C. 2001 *et seq.*), Congress delegated to the Secretary of Transportation authority to specify waters on which certain Inland Navigation Rules apply in order to best meet the navigational needs in these areas. The Secretary of Transportation delegated this authority to the Coast Guard (49 CFR 1.46(n)(14)).

In 1989, the American Waterways Operators, Inc., representing many of the towboat operators, raised concerns about glare and reflection of the masthead lights off of large tows when pushing ahead on the Gulf Intracoastal Waterway. Based on recommendations from both the Navigation Safety Advisory Council and the Towing Safety Advisory Council, the Coast Guard is amending 33 CFR part 89 so that Inland Rule 24(i) will apply to specified portions of the Gulf Intracoastal Waterway. This will allow towboat operators to extinguish their masthead lights, except when approaching or crossing certain designated ship channels.

Discussion of Comments and Changes

The Coast Guard received four comments in response to the proposed rule. Comments from the American Waterways Operators and American Commercial Barge Line Company strongly endorsed the rule.

One comment requested that the Coast Guard define the terms "EHL" and "WHL" as used in the proposed rule. The final rule indicates that the terms are acronyms for "East of Harvey Locks" and "West of Harvey Locks" and denote mile marks. The same comment also noted that the Cochrane Bridge, referenced in § 89.25(f), was replaced in 1985 and questioned whether the replacement bridge carries the name of the previous bridge. The Coast Guard has verified that the replacement bridge carries the same name.

The same comment also suggested that the Coast Guard more stringently enforce existing lighting standards for tow vessels on the Gulf Intracoastal Waterway. The Coast Guard has long recognized the problem of adequate sidelights on barges. These enforcement concerns will be forwarded to local Coast Guard Districts. However, since towboat operators on the Gulf Intracoastal Waterway almost exclusively push ahead, their barges are lighted not only with side lights but with a special flashing yellow light in accordance with Inland Rule 24(f)(i). Therefore, the Coast Guard has determined that barges will be sufficiently lighted under these rules to meet the navigational needs of the Gulf Intracoastal Waterway.

Another comment expressed concern that the Coast Guard would include questions about the twelve designated areas along the Gulf Intracoastal Waterway on future licensing exams. Questions concerning licensing and testing are beyond the scope of this rulemaking. A copy of the comment, however, has been forwarded to the appropriate Coast Guard authority.

Regulatory Evaluation

This rule is not major under Executive Order 12291 and not significant under the "Department of Transportation Regulatory Policies and Procedures" (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. No additional costs will be incurred. This rule merely requires white masthead lights to be turned on and off at appropriate points along the Gulf Intracoastal Waterway, for safety reasons.

Small Entities

No comments were received regarding the impact of the rule on small entities. This rule exempts towboat operators from using white masthead lights on designated portions of the Gulf Intracoastal Waterway. This rule will impose no additional costs. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Under Federal law, authority to issue regulations to implement the Inland Navigational Rules is vested in the Secretary of Transportation and delegated to the Coast Guard. Therefore, the Coast Guard intends this rule to preempt State action addressing this subject matter.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2 of

Commandant Instruction M16475.1B, this rulemaking is categorically excluded from further environmental documentation. This rule exempts towboat operators from using white masthead lights on designated portions of the Gulf Intracoastal Waterway and clearly will have no impact on the environment. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under "ADDRESSES."

List of Subjects in 33 CFR Part 89

Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 89 as follows:

PART 89—INLAND NAVIGATION RULES: IMPLEMENTING RULES

1. The authority citation for part 89 continues to read as follows:

Authority: 33 U.S.C. 2071; 49 CFR 1.46(n)(14).

2. Section 89.25 is revised to read as follows:

§ 89.25 Waters upon which Inland Rules 9(a)(ii), 14(d), and 15(b) apply.

Inland Rules 9(a)(ii), 14(d), and 15(b) apply on the Great Lakes, the Western Rivers, and the following specified waters:

(a) Tennessee-Tombigbee Waterway.

(b) Tombigbee River.

(c) Black Warrior River.

(d) Alabama River.

(e) Coosa River.

(f) Mobile River above the Cochrane Bridge at St. Louis Point.

(g) Flint River.

(h) Chattachoochee River.

(i) The Apalachicola River above its confluence with the Jackson River.

3. Section 89.27 is added to read as follows:

§ 89.27 Waters upon which Inland Rule 24(i) applies.

(a) Inland Rule 24(i) applies on the Western Rivers and the specified waters listed in § 89.25 (a) through (i).

(b) Inland Rule 24(i) applies on the Gulf Intracoastal Waterway from St. Marks, Florida, to the Rio Grande, Texas, including the Morgan City-Port Allen Alternate Route and the Galveston-Freeport Cutoff, except that a power-driven vessel pushing ahead or towing alongside shall exhibit the lights required by Inland Rule 24(c), while transiting within the following areas:

(1) St. Andrews Bay from the Hathaway Fixed Bridge at Mile 284.6 East of Harvey Locks (EHL) to the DuPont Fixed Bridge at Mile 295.4 EHL.

(2) Pensacola Bay, Santa Rosa Sound and Big Lagoon from the Light "10" off of Trout Point at Mile 176.9 EHL to the Pensacola Fixed Bridge at Mile 189.1 EHL.

(3) Mobile Bay and Bon Secour Bay from the Dauphin Island Causeway Fixed Bridge at Mile 127.7 EHL to Little Point Clear at Mile 140 EHL.

(4) Mississippi Sound from Grand Island Waterway Light "1" at Mile 53.8 EHL to Light "40" off the West Point of Dauphin Island at Mile 118.7 EHL.

(5) The Mississippi River at New Orleans, Mississippi River-Gulf Outlet Canal and the Inner Harbor Navigation Canal from the junction of the Harvey Canal and the Algiers Alternate Route at Mile 6.5 West of Harvey Locks (WHL) to the Michoud Canal at Mile 18 EHL.

(6) The Calcasieu River from the Calcasieu Lock at Mile 238.6 WHL to the Ellender Lift Bridge at Mile 243.6 WHL.

(7) The Sabine Neches Canal from mile 262.5 WHL to mile 291.5 WHL.

(8) Bolivar Roads from the Bolivar Assembling Basin at Mile 346 WHL to the Galveston Causeway Bridge at Mile 357.3 WHL.

(9) Freeport Harbor from Surfside Beach Fixed Bridge at Mile 393.8 WHL to the Bryan Beach Pontoon Bridge at Mile 397.6 WHL.

(10) Matagorda Ship Channel area of Matagorda Bay from Range "K" Front Light at Mile 468.7 WHL to the Port O'Connor Jetty at Mile 472.2 WHL.

(11) Corpus Christi Bay from Redfish Bay Day Beacon "55" at Mile 537.4 WHL when in the Gulf Intracoastal Waterway main route or from the north end of Lydia Ann Island Mile 531.1A when in the Gulf Intracoastal Waterway Alternate Route to Corpus Christi Bay LT 76 at Mile 543.7 WHL.

(12) Port Isabel and Brownsville Ship Channel south of the Padre Island Causeway Fixed Bridge at Mile 665.1 WHL.

Dated: April 9, 1993.

W.J. Ecker,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc 93-10960 Filed 5-7-93; 8:45 am]

BILLING CODE 4910-14-M

federal register

Monday
May 10, 1993

Part III

Department of Transportation

Coast Guard

33 CFR Part 164
46 CFR Part 35
Navigation Underway: Tankers; Final Rule

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 164

46 CFR Part 35

[CGD 91-203, 91-204, 91-222]

RIN 2115-AE00, AE03, AE12

Navigation Underway; Tankers

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is consolidating three proposed rules into one final rule requiring tankers of 1,600 or more gross tons (GT) when operating on the navigable waters of the United States to navigate with two officers on the bridge and an adequate engineering watch, including a licensed engineer in the machinery spaces. Restrictions are also imposed on use of an auto pilot by these tankers. These actions are required by statute. This final rule will provide additional tanker navigation safety requirements to reduce the incidence of tanker casualties.

EFFECTIVE DATE: This regulation is effective on July 9, 1993. The Director of the Federal Register approves as of July 9, 1993. The incorporation by reference of certain publications listed in the regulations.

FOR FURTHER INFORMATION CONTACT: Ms. Margie Hegy, Short Range Aids to Navigation Division, (G-NSR-3), 267-0415.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Lieutenant Commander Paul Jewell, Project Manager, OPA 90 staff and Joan Tilghman, Project Counsel, OPA 90 staff.

Regulatory History

This final rule combines three related Coast Guard rulemakings that were published separately. Those rulemakings were: "Use of Automatic Pilot: Area Restrictions and Performance Requirements" (CGD 91-204), "Unattended Machinery Spaces: Operating Requirements" (CGD 91-203), and "Second Officer on the Bridge" (CGD 91-222).

On January 3, 1992, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled "Tank Vessels: Automatic Pilot Use; Area Restrictions and Performance Requirements" in the **Federal Register** (57 FR 514). The Coast Guard received 26 letters commenting on the proposal. Because of the comments received, a supplemental notice of proposed rulemaking (SNPRM) was published on October 2, 1992, entitled "Use of Automatic Pilot: Area Restrictions and Performance Requirements" (57 FR 45667). Seventeen letters were received commenting on the SNPRM. Both of these rulemaking documents proposed to designate waters where certain rank vessels would be allowed to operate with the auto pilot engaged.

On April 9, 1992, the Coast Guard published a NPRM entitled "Unattended Machinery Spaces: Operating Requirements" in the **Federal Register** (57 FR 12378). That NPRM proposed to allow certain tankers to operate with unattended machinery spaces. The Coast Guard received 159 letters commenting on the proposal. Most of those letters objected to the proposal, and on October 2, 1992, the Coast Guard published a SNPRM. The SNPRM proposed to require the machinery spaces to be attended continuously. The Coast Guard received 10 letters commenting on the SNPRM.

On October 2, 1992, the Coast Guard also published a NPRM entitled "Second Officer on the Bridge" in the **Federal Register** (57 FR 45664). The NPRM proposed to require that two licensed officers be on the bridge of certain tankers when in the internal waters of the U.S. The Coast Guard received 27 letters commenting on this proposal.

No public hearings were requested for the most recent rulemakings and none was held.

Background and Purpose

The Oil Pollution Act of 1990 (OPA 90) (Pub. L. 101-380) requires a number of tanker navigation safety rules. Section 4114(a) of OPA 90 directs the Coast Guard to define the conditions under, and designate the waters upon, which tank vessels subject to 46 U.S.C. 3703 may operate with the auto pilot engaged or with an unattended engine room. For tankers 1,600 GT or more subject to 46 U.S.C. 8502, section 4116(b) directs the designation of U.S. waters where a second officer must be on the bridge.

The Coast Guard has determined that this rule should also apply to foreign flag tankers and U.S. tankers sailing on registry because these tankers pose a similar risk to the environment as tankers subject to 46 U.S.C. 8502. Therefore, under the authority of section 12 of the Ports and Waterways Safety Act (33 U.S.C. 1231) and 46 U.S.C. 8502 this final rule applies to all tankers of 1,600 GT or more when in the navigable waters of the United States. This rule: (1) Designates areas where automatic pilots may be used; (2) prohibits operation with unattended machinery spaces; and (3) requires the tankers to navigate with at least two officers on the bridge.

Discussion of Comments and Changes

A number of the comments received addressed the three proposed rules in general and also provided specific comments on the individual provisions of the proposed rules. The majority of the comments supported the proposed rules, and many stated that the Coast Guard should extend the rules to include other vessels. The reason given was that navigation safety rules are appropriate not only for tankers but for all vessels that pose a risk to the environment.

There were a number of comments that addressed specifically including both towing vessels and barges under the rules because they also pose a risk to the environment. Some of the comments stated that Congress clearly intended these rules to apply to towing vessels. There also were comments that supported excluding towing vessels and barges from the scope of the rules because towing vessels are operated differently from tankers. These latter comments stated that applying the rules to towing vessels would increase operating expenses without a commensurate increase in safety or would adversely affect the safety of towing vessels and tank barges.

OPA 90 requires that the Coast Guard designate waters where most tankers must navigate with additional navigational safeguards. Congress expressed its desire that the Coast Guard implement these rules for tankers in an expeditious manner. The Coast Guard does not want to delay further the implementation of the tanker-specific rules to include other vessels, but may consider initiating a separate rulemaking under other authority to expand the applicability of the requirements set out in the final rule.

The proposed rules referred separately to tankers and integrated tug and barge units (ITBs) certificated to operate as tankships. ITBs inspected and certificated to operate as tankships are considered by the Coast Guard to fall within the definition of tanker. Consequently, it is not necessary to designate ITBs as a separate and distinct category of tanker. Language specifically defining ITBs as tankers is included in the final rule.

One comment requested the Coast Guard to clarify whether the three proposed rules applied to foreign tankers enroute to Canadian ports and transiting U.S. waters in the Strait of Juan de Fuca.

U.S. waters in the Strait of Juan de Fuca are internal waters of the United States. Tankers transiting the internal waters of the U.S. are subject to this rule. The principle of innocent passage only applies to vessels transiting the territorial seas of the U.S.

Unattended Machinery Spaces

Most of the comments agreed that tankers should operate with a licensed engineer in the machinery spaces. One comment stated that tankers should be prohibited from operating with their machinery spaces unattended out to twelve nautical miles from shore.

Section 4114(a) of OPA 90 specifies that this rule applies only on the navigable waters of the United States. As defined in 33 U.S.C. 2701, navigable waters are the waters of the United States, including the territorial sea. This rule cannot be extended out to twelve miles under section 4114(a), because the territorial sea extends only three miles from the territorial sea baseline. Extending the applicability of this rule under other authority may be the subject of a later Coast Guard action. The final rule sets requirements for those areas that Congress believed merited special attention.

Three comments stated that the rule should not require the engineer to be in a specific location, because there are instances when the licensed engineer's presence in the main control space or some other location within the machinery spaces would be more appropriate.

The purpose of the rule is to ensure that a licensed engineer is monitoring the engineering system's performance and is available to take immediate corrective action when necessary. A restrictive reading of the International Maritime Organization (IMO) definition of machinery spaces could lead to the conclusion that the engineer's presence in the main control station is not sufficient to comply with this rule. However, such a limited scope is not consistent with the Coast Guard's intent. The final rule has been clarified to allow the licensed engineer to monitor the systems and take the necessary corrective action from the main control station.

The majority of comments to both the NPRM and SNPRM endorsed having a licensed engineer in the machinery spaces when a tanker is transiting any navigable waters of the U.S. One comment stated that tankers should be permitted to operate with unattended machinery spaces when in the territorial sea except in specified high risk areas. Another comment said that having a licensed engineer in the machinery spaces of highly automated vessels would not improve safety. That comment indicated that certain automated vessels with safety features beyond the minimum requirements prescribed for automated plant certification, should be allowed to operate without an engineer attending the machinery spaces. For safety reasons the Coast Guard believes that most tankers in the navigable waters of the U.S. should have a licensed engineer immediately available in the machinery spaces to respond to alarms and take manual control when necessary.

Second Officer on the Bridge

Fourteen comments supported the provision requiring two officers on the bridge. Many of those comments stated that navigating with two licensed officers on the bridge when the vessel was operating in pilotage waters was already a common maritime practice required by most tanker owners.

Two comments did not support the proposed rulemaking. One comment stated that two officers were not necessary as long as the one officer on watch was well rested, competent, and qualified. The other comment felt that an additional officer would be a distraction to the person piloting the vessel.

Standard maritime practice dictates that two officers be on the bridge when a tanker is in pilotage waters. More importantly, in OPA 90 Congress has recognized the difficulty and complexity of tanker navigation close to shore by requiring the Coast Guard to designate waters where having a second licensed officer will facilitate safe operations.

One comment letter expressed neither explicit support nor opposition to the rule but cited a list of tanker casualties that occurred with two officers on the bridge. Another comment questioned whether any recent tanker casualties occurred because there was only one officer on the bridge.

The Coast Guard recognizes that there have been tanker casualties that have occurred with two or more officers on the bridge. However, there are recent instances where tanker casualties occurred due to error by the sole licensed deck officer on watch. The T/V WORLD PRODIGY grounding and spill in 1989 is an example of the type of accident that this rule should help prevent.

One comment stated that the rule should use the term "licensed deck officers" to preclude using other licensed officers, such as engineering or radio officers, in complying with this rule. A similar comment stated that the duties of the two officers should be specified, because the rule as written would allow either officer to be sleeping as long as both were presented on the bridge. Another comment questioned whether the pilot was considered a licensed officer for the purposes of this rule.

The Coast Guard has revised the terminology in the second officer provision of this rule to specify that two licensed deck officers must be "on watch" on the bridge to ensure that both of these officers are serving in an official capacity and not sleeping or performing other tasks unrelated to the navigation of the tanker. The rule now specifies that in waters where a pilot is required, the master or a mate must be on the bridge along with the pilot. The rule will allow one officer to concentrate on the safe movement of the tanker through the waterway, while the other officer assists as necessary with navigation and performs other important watch functions. In areas where pilots are not required, at least two licensed deck officers must be on the bridge to navigate the tanker safely.

The NPRM stated that in fifteen States, a foreign flag or U.S. registered vessel is required only to pay a pilotage fee in the State's pilotage waters. Some comments read this statement as the Coast Guard's interpretation of pilotage laws. One comment believed the Coast Guard endorsed this practice.

The Coast Guard is aware of fifteen States which do not have compulsory pilotage laws and mentioned that fact to dispel any notion that foreign trade tankers were already required to navigate with two licensed officers on the bridge. The Coast Guard's description of existing practices is not an endorsement.

A number of the letters supporting the second officer provision stated that a second officer should be required in all navigable waters of the U.S. The comments stated that extending the requirement to all navigable waters would reflect good marine practice, would ensure that an additional officer is assisting with the navigation in the generally congested areas at the entrance to harbors, and would make the final rule less confusing to the mariner. This change would also make the second officer provision consistent with the applicability of the unattended machinery spaces and auto pilot provisions of the rule.

The Coast Guard agrees with the comments and has removed the limitation to internal waters from § 164.13(c) thus making the rule subject to the general applicability provisions of § 164.01, which includes all navigable waters of the U.S., (except the St. Lawrence Seaway). This will not be a substantial added burden, because the requirement would add only a small additional time (20 minutes at nine knots) during the voyage when two officers would be required to be on the bridge. It also should increase the likelihood that the tanker will navigate safely in what are generally congested approaches to U.S. harbors. The impact of this change on vessels certificated only for Great Lakes service or Lakes, Bays, and Sounds (LBS) service is discussed below.

One letter stated that the second officer requirement should apply when a tanker is within one-half hour steaming time from shore, because there are rocks and shoals that far out to sea. The final rule applies in the navigable waters of the U.S. A rule which applies when a vessel is one-half hour steaming time from shore would be inexact and confusing to mariners and enforcement officers alike. Because such a standard would vary with each tanker, and possibly extend beyond the navigable waters of the U.S., the Coast Guard did not incorporate the suggestion into the rule.

One comment noted that having two officers on the bridge when approaching port is something that vessels have done for 100 years. The comment stated that instead of implementing the rule, the Coast Guard should require tankers to hire a local quartermaster to steer the vessel, arguing that local quartermasters would greatly enhance safety in U.S. waterways.

The person steering the tanker, whether a local quartermaster or a member of this ship's crew, should follow the directions of the watch officer or pilot. The helmsman should neither be expected, nor allowed, to make decisions regarding the helm commands or courses steered, but should only execute the steering commands given. Consequently, the Coast Guard does not believe that requiring a local quartermaster would result in safer navigation than navigating with two licensed officers. The Coast Guard does not intend to require tanker masters to hire a local quartermaster to steer the vessel.

Seven comments were received that discussed the proposed exemption for small tankers certificated only for operation on Great Lakes service or Lakes, Bays, and Sounds (LBS) service. All but one of the comments agreed that small tankers should be exempt from the rule; and four stated that the exemption be extended to include other small, special purpose tankers with limited areas of operation. Some comments argued, however, that factors other than the certificate of inspection should be considered when determining which tankers to exempt. Small tanker owners and operators noted that, because of the OPA 90-mandated work-hour limitations, the second officer rule could be economically devastating. The owners would have to double the deck officer complement and modify their vessels to accommodate the extra officers. The comments stated that the rule would not increase the safety of the small tankers because of tanker size, limited routes, and officer familiarity with the waters navigated.

The Coast Guard does not wish to impose an undue burden on operators of small tankers. For the reasons set out in the NPRM, the Coast Guard continues to believe that small coastal tankers on limited routes pose less risk to health, safety, and the environment than other tankers. However, a blanket exemption for Great Lakes and LBS services could allow a large tanker to change its route and become exempt from the rule simply because of its certificate. Such an exemption would be inappropriate. Consequently, the provision in the proposed rule that exempted all tankers certificated to operate only on the Great Lakes or only on Lakes, Bays, and Sounds routes has been eliminated. Instead, Coast Guard COTPs will consider deviations from the rule on a case-by-case basis. A deviation may be granted, if it does not impair the safe navigation of the vessel. The procedure by which a tanker owner or operator may request a deviation is specified in 33 CFR 164.55.

The rule is intended to match the cost of compliance with the benefit to be gained. In striking a balance, the Coast Guard believes it is appropriate to take account of the relative risks posed by large and small tankers. For the reasons set out above, the best approach for achieving a cost/benefit balance for small tankers is to let the cognizant COTP assess the risks and grant deviations to specific vessels or transits as appropriate.

Use of Auto Pilots

Comments stated that the auto pilot rule should apply to all tank vessels regardless of cargo or size because all tank vessels pose risks. One comment stated that if a helmsman was not required to be present, an auto pilot failure on a small tank vessel could cause the vessel to ground or collide with another vessel, perhaps resulting in a major spill.

In the auto pilot SNPRM, the Coast Guard proposed to remove 46 CFR 35.20–45, which governs the use of auto pilots by all tank ships, and to add, in 33 CFR 164.13, stringent restrictions on auto pilot use by a limited class of tank vessel. Because 33 CFR part 164 applies only to vessels of 1,600 GT or more, the use of an auto pilot by tank ships of less than 1,600 GT would have been unrestricted. The Coast Guard agrees that small tank ships should be required to exercise appropriate care when using an auto pilot. Consequently, 46 CFR 35.20–45 is retained with a cross reference to the more restrictive rules in 33 CFR 164.13 for tankers of 1,600 GT or more. Title 46 CFR 35.20–45 requires the master of a tank ship to ensure that when the auto pilot is used in certain areas or circumstances that: (1) It is possible to immediately establish manual control; (2) a competent person is ready to take over steering control and; (3) the changeover from automatic to manual steering is made by, or under the supervision of, the officer of the watch. The final rule adds auto pilot restrictions to 33 CFR 164.13 for tankers of 1,600 GT or more. These restrictions include a prohibition on auto pilot use in certain designated areas and a requirement that a qualified helmsman be stationed at the helm.

One comment generally agreed with the auto pilot SNPRM, but suggested modification to allow Captains of the Port (COTPs) discretion in permitting certain vessels with an auto pilot that is part of an integrated navigation system to operate without restriction.

In the auto pilot SNPRM, the Coast Guard proposed that certain tankers with integrated navigation systems be allowed to operate with such systems engaged even in traffic separation schemes and shipping safety fairways where use of an auto pilot was otherwise prohibited. This provision is retained in the final rule. Anchorage grounds and areas within one half mile from shore were not added to the list of areas where the integrated systems could be used, because the variety of circumstances that could be encountered in those areas make it undesirable to grant blanket approval to the use of integrated systems. Tankers in anchorage grounds or that are within one half mile from shore are generally maneuvering at a slow speed where an auto pilot would not be effective.

Two comments stated that the COTPs also should have discretion to restrict the use of an auto pilot in additional waters within the COTP zone. The Coast Guard does not agree. It is in the mariner's and the Coast Guard's interest to minimize the prospect of a confusing array of rules that may vary from port to port. The Coast Guard finds that a single, national rule will facilitate compliance.

A number of comments did not agree that the one-half mile from shore restriction on the use of an auto pilot was adequate because there would not be sufficient time to correct an auto pilot failure. The comments suggested restricting the use of an auto pilot to greater distances from shore.

The Coast Guard does not agree that the time required to correct an auto pilot failure is a significant safety consideration. This rule requires a helmsman to be present and ready at all times to take manual control. It takes a similar amount of time to override a modern auto pilot and take manual steering control as it does to make a course change by turning the wheel.

Some comments stated that the use of an advanced auto pilot in certain waters, such as dredged channels, should not be permitted. The comments cited other unique circumstances in specific local areas of operation (such as the Florida Keys, New York/New Jersey harbor, or Delaware Bay) where the use of an auto pilot would be allowed under this rule but would be unsafe because of specific existing conditions.

The steering of a tanker is affected by the distance from the hull to bottom of the channel. The amount of underkeel clearance and its affect on steering depend on the draft of a tanker and the depth of the water. Some, but not all, tankers have so little underkeel clearance in dredged channels that they should not operate in these channels with their auto pilot engaged. It is the duty of vessel masters and pilots to exercise their professional judgment and weigh the capabilities of the auto pilot and the specific navigational demands in a local area. Vessel masters and pilots are in the best position to determine whether, in the waters where the final rule allows discretion, the use of an auto pilot is safe based on the local conditions. There is nothing in this rule that compels a tanker's master or pilot to use an auto pilot, and the Coast Guard is not promoting indiscriminate use of an auto pilot. This rule is permissive and recognizes that an auto pilot is a navigational tool that, when used by a prudent mariner under appropriate circumstances, can assist the mariner in the safe transit of a tanker.

Most comments supported the requirement that a qualified individual be present at the helm when a tanker is operating with the auto pilot engaged while on the navigable waters of the U.S. One dissenting comment suggested that the boredom of the helmsman and resulting inattention outweighed the safety advantages of having a qualified individual at the helm. Another dissenting comment stated that having a helmsman defeats the purpose of an auto pilot.

Under current regulations (33 CFR 164.11), there must be a person competent to steer the vessel in the wheelhouse at all times. Because of the risk tankers pose to the environment, the Coast Guard does not agree the qualified helmsman on tankers of 1,600 gross tons or more should be allowed to engage in other duties elsewhere on the bridge when the auto pilot is engaged pursuant to this rule. Having a qualified helmsman at the helm ensures that someone is immediately available to disengage the auto pilot and take manual steering control in an emergency.

The statute cited in the footnote of 33 CFR 164.11 has been superseded. The Coast Guard has added a provision in this rule to correct that footnote.

Some of the comments noted that the Coast Guard's statement in the SNPRM that licensed deck officers sometimes serve as helmsman was not true and that we should prohibit this practice. The Coast Guard knows that it would be unusual for a large tanker to have the licensed deck officer serving as helmsmen. The discussion of the issue in the SNPRM focused on a limited group of small tankers that have limited space in the pilothouse and that are not required to carry individuals qualified to serve as helmsman. The Coast Guard does not believe that it is appropriate to prohibit a licensed deck officer, master, or pilot from steering a tanker.

Incorporation by Reference

The Director of the Federal Register has approved the material in 33 CFR 164.03 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. The material is available as indicated in that section.

Regulatory Evaluation

This rule is not major under Executive Order 12291 and not significant under the "Department of Transportation Regulatory Policies and Procedures" (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of the rule to be so minimal that a full Regulatory Evaluation is unnecessary. The rule does not meet any of the criteria listed in paragraph 6(a)(2) of the Executive Order. This rule will not result in annual costs of $100 million; will have no significant adverse effects on competition, employment, or other aspects of the economy; and will not result in a major increase in costs and prices.

The rule will affect tankers of 1,600 GT or more. Tankers must comply with this rule only when underway on the navigable waters of the United States, which extends out to 3 nautical miles seaward from the territorial sea baseline. The comments received on the NPRMs and SNPRMs support the Coast Guard's position that the provisions of the rule, in large part, codify generally accepted marine practice. According to the comments, most tanker masters already ensure that a licensed engineer is attending the machinery spaces and that more than one deck officer is on the bridge when underway in most of the navigable waters of the United States.

There will be no cost to vessel owners in complying with the automatic pilot provisions of the rule, because the rule does not require the use of auto pilots, it only prohibits their use in certain areas. The rule neither requires equipment nor increases crew size.

There were comments from owners of small tankers who indicate that the second officer requirement would cost as much as $100,000 per year for a tanker. The Coast Guard is aware of 10 small tankers that will be subject to this rule, and consequently, subject to higher operating costs. If all ten of these tanker owners were to spend $100,000 per year to provide additional deck watch officers, this rule would cost about $1 million per year. The owners of small tankers are free to request deviation from the rule which could significantly reduce the costs of compliance.

The overall potential benefit of the rule is that it will provide increased protection from oil spills for U.S. shores and adjacent waters. However, it is not possible to predict the number of casualties that will be prevented or the amount of oil that would be spilled. If even one moderate spill in an environmentally sensitive area is prevented, the benefits are expected to outweigh the costs. Requiring two licensed officers on the bridge of tankers reduces the likelihood that a serious navigational error will occur or go unnoticed. Requiring a licensed engineer on watch in the machinery spaces or the main control space will ensure prompt attention to machinery faults. Restricting the use of automatic pilots will promote increased vigilance and quick helm response to emergency situations in restricted waters.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). "Small entities" also include small not-for-profit organizations and small governmental jurisdictions.

The portion of this rulemaking that requires tankers over 1,600 gross tons to operate in the navigable waters of the United States with at least two licensed deck officers on watch on the bridge may result in increased operating costs for vessels in coastwise trading and would likely be the only potential economic impact of interest to small entities. Of particular concern to the Coast Guard were 10 of the smallest tankers that are subject to this rule. The Coast Guard's analysis of its records indicates that none of these 10 vessels are operated by small businesses. Operators include several multinational oil companies, a large Federal agency, a Great Lakes ore fleet operator, and a firm that owns and operates a fleet of 25 ships and 600 barges. Although two firms forwarded comments that expressed economic concerns about effects of the second officer requirement, neither were small businesses. No comments on economic effects were received from small entities.

Additionally, existing provisions for deviations could effectively tier the regulation, were small entities to engage in trade regulated by this rule. While the Coast Guard did not include specific exemptions, Coast Guard COTPs are authorized to consider requests for deviations from the rule on a case-by-case basis. A deviation may be granted if granting the deviation does not impair the safe navigation of the vessel. The procedure by which a tanker owner or operator may request a deviation is specified in 33 CFR 164.55. Beyond the deviation procedures, further flexibility would not be in the interest of sound environmental policy.

Because the portions of this rule concerning unattended machinery spaces and the use of auto pilots will impose virtually no costs on the regulated community, and because of the circumstances described in this discussion on small entities concerning the second officer requirement, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

The rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed the rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The Coast Guard received a number of comments on its preemption determination, some in support and some in opposition. While a tanker covered by this rule is operating on the navigable waters of the U.S., the rule: (1) Prohibits the operation with unattended machinery spaces; (2) requires that a qualified individual be at the helm; and (3) requires two officers to be on the bridge. It is a well-settled principle that regulations concerning manning of commercial vessels in U.S. waters are the exclusive domain of the U.S. Coast Guard. Further, standardizing vessel manning requirements is necessary because vessels move from port to port in the national marketplace, and variation of manning requirements would be unreasonably burdensome. Therefore, the Coast Guard intends the manning provisions to preempt State action addressing the same subject matter. This rule does not alter the State-Federal relationship regarding pilotage requirements and does not preempt the States' authority to establish a requirement for a State pilot under 46 U.S.C. 8501.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that preparation of an Environmental Impact Statement is not necessary. An Environmental Assessment and a Finding of No Significant Impact are available in the docket for inspection or copying where indicated under "ADDRESSES." The rule is not expected to result in significant impact on the quality of the human environment, as defined by the National Environmental Policy Act.

In evaluating the environmental impact of this action, the Coast Guard considered the following:

(1) Environmental benefits of regulating the use of auto pilots or requiring additional manning on the bridge or in the machinery spaces cannot be quantified in isolation, due to the complementary effects of other OPA 90-related regulatory changes. For example, regulations dealing with improved crew training, vessel traffic control, and other OPA 90 initiatives should result in reduced casualties and reduced numbers and volumes of spills;

(2) The rule involves the navigable waters of the U.S. and should help prevent spills, especially when vessels are maneuvering near shorelines and in congested waterways.

List of Subjects

33 CFR Part 164

Incorporation by reference, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

46 CFR Part 35

Cargo vessels, Marine safety, Navigation (water), Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 164 and 46 CFR part 35 as follows:

TITLE 33 CFR—[AMENDED]

PART 164—NAVIGATION SAFETY REGULATIONS

1. The authority citation for part 164 is revised to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. 2103, 3703; 49 CFR 1.46. Sec. 164.13 also issued under 46 U.S.C. 8502 sec. 4114(a), Pub. L. 101–380, 104 Stat. 517 (46 U.S.C. 3703 note). Sec. 164.61 also issued under 46 U.S.C. 6101.

2. Section 164.03 is revised to read as follows:

§ 164.03 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in paragraph (b) of this section, the Coast Guard must publish notice of change in the Federal Register and the material must be available to the public. All approved material is on file at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC, and at the U.S. Coast Guard, Marine Environmental Protection Division (G–MEP), room 2100, 2100 Second Street, SW., Washington, DC 20593–0001 and is available from the sources indicated in paragraph (b) of this section.

(b) The material approved for incorporation by reference in this part and the sections affected are as follows:

Radio Technical Commission for Maritime Services (RTCM)

P.O. Box 19087, Washington, DC 20036, Paper 12–78/DO–100, Minimum Performance Standards, Loran C Receiving Equipment, 12/20/77—164.41

International Maritime Organization (IMO)

4 Albert Embankment, London SE1 7SR, U.K., IMO Resolution A.342(IX), Recommendation on Performance Standards for Automatic Pilots, adopted November 12, 1975—164.13

3. The footnote in § 164.11 is revised to read as follows:

[1] See also 46 U.S.C. 8702(d), which requires an able seaman at the wheel on U.S. vessels of 100 gross tons or more in narrow or crowded waters during low visibility.

4. Section 164.13 is added to read as follows:

§ 164.13 Navigation underway: tankers.

(a) As used in this section, "tanker" means a self-propelled tank vessel, including integrated tug barge combinations, constructed or adapted primarily to carry oil or hazardous material in bulk in the cargo spaces and inspected and certificated as a tanker.

(b) Each tanker must have an engineering watch capable of monitoring the propulsion system, communicating with the bridge, and implementing manual control measures immediately when necessary. The watch must be physically present in the machinery spaces or in the main control space and must consist of at least a licensed engineer.

(c) Each tanker must navigate with at least two licensed deck officers on watch on the bridge, one of whom may be a pilot. In waters where a pilot is required, the second officer, must be an individual licensed and assigned to the vessel as master, mate, or officer in charge of a navigational watch, who is separate and distinct from the pilot.

(d) Except as specified in paragraph (e) of this section, a tanker may operate with an auto pilot engaged only if all of the following conditions exist:

(1) The operation and performance of the automatic pilot conforms with the standards recommended by the International Maritime Organization in IMO Resolution A.342(IX).

(2) A qualified helmsman is present at the helm and prepared at all times to assume manual control.

(3) The tanker is not operating in any of the following areas:

(i) The areas of the traffic separation schemes specified in subchapter P of this chapter.

(ii) The portions of a shipping safety fairway specified in part 166 of this chapter.

(iii) An anchorage ground specified in part 110 of this chapter.

(iv) An area within one-half nautical mile of any U.S. shore.

(e) A tanker equipped with an integrated navigation system, and complying with paragraph (d)(2) of this section, may use the system with the auto pilot engaged while in the areas described in paragraphs (d)(3) (i) and (ii) of this section. The master shall provide, upon request, documentation showing that the integrated navigation system—

(1) Can maintain a predetermined trackline with a cross track error of less than 10 meters 95 percent of the time;

(2) Provides continuous position data accurate to within 20 meters 95 percent of the time; and

(3) Has an immediate override control.

TITLE 46 CFR—[AMENDED]

PART 35—OPERATIONS

5. The authority citation for part 35 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3306, 3703, 6101; 49 U.S.C. App. 1804; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

6. In § 35.20–45, the introductory text is revised to read as follows:

§ 35.20–45 Use of Auto Pilot—T/ALL.

Except as provided in 33 CFR 164.13, when the automatic pilot is used in:

* * * * *

Dated: May 4, 1993.

A. Cattalini,

Captain, U.S. Coast Guard, Acting Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 93–10959 Filed 5–7–93; 8:45 am]

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May 10, 1993

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 310

Status of Certain Over-the-Counter Drug Category II and III Active Ingredients; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 91N-0505]

RIN 0905-AA06

Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing that certain active ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this final rule after considering the reports and recommendations of various OTC advisory review panels and public comments on the agency's notices of proposed rulemaking. Based on the absence of substantive comments in opposition to the agency's proposed nonmonograph status for these ingredients, as well as the absence of submissions by interested parties of new data or information to FDA pursuant to the regulations, the agency is issuing this final rule to remove from the OTC market these ingredients for the uses specified in this rule. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: November 10, 1993.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In various issues of the **Federal Register**, FDA has published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking to establish monographs for specific classes of OTC drug products, together with the recommendations of the OTC advisory review panels, which were responsible for evaluating data on the active ingredients in the specific drug class(es) in each proposed monograph. Following publication of each proposed monograph, interested parties were invited to submit comments within a set time period, with an additional period of time allowed for reply comments in response to comments filed in the initial comment period.

FDA evaluated the OTC advisory review panels' recommendations and the comments and reply comments received in response to the initial publication of the advance notices of proposed rulemaking. After considering this information, the agency published proposed regulations (in the form of tentative final monographs for various specific classes of OTC drug products). Interested persons were invited to file comments, objections, and/or requests for an oral hearing before the Commissioner of Food and Drugs (the Commissioner) regarding the specific proposals within a set time period. A period of 12 months was provided for the submission of new data and information regarding each specific proposed rulemaking, and 2 additional months were provided for comments on the new data. The publication dates, comment closing dates, and new data closing date for each advance notice of proposed rulemaking and notice of proposed rulemaking are listed in Table I of the August 25, 1992 proposed rulemaking discussed below. (See 57 FR 38568 at 38569.)

In the **Federal Register** of August 25, 1992 (57 FR 38568), FDA published, under § 330.10(a)(7)(ii) (21 CFR 330.10(a)(7)(ii)), a proposed rulemaking encompassing certain Category II and III active ingredients for which the periods for submission of comments and new data following the publication of a notice of proposed rulemaking had closed and for which no significant comments or new data to upgrade the status of these ingredients had been submitted. In each instance, a final rule for the class of ingredients involved had not been published to date. Since that time, final rules for two of the OTC drug rulemakings included in the proposal, external analgesic drug products for diaper rash and topical antifungal drug products for diaper rash, were published on December 18, 1992 (57 FR 60426 and 60430, respectively). Accordingly, the active ingredients from those rulemakings that were included in the proposal are not included in this final rule.

The OTC drug review administrative procedures provide in § 330.10(a)(7)(ii) that the Commissioner may publish a separate tentative order proposing that active ingredients be excluded from an OTC drug monograph on the basis of the Commissioner's determination that they would result in a drug product not being generally recognized as safe and effective or would result in misbranding. This order may include active ingredients for which no substantial comments in opposition to the advisory panel's proposed classification and no new data and information were received pursuant to § 330.10(a)(6)(iv) (21 CFR 330.10(a)(6)(iv)). Section 330.10(a)(7)(ii) authorizes the publication of a separate tentative order immediately following the close of the comment and new data periods for an advance notice of proposed rulemaking. However, in the case of the ingredients included in the proposal, the Commissioner waited until after proposed rulemakings were published and the periods for submission of comments and new data had ended. This additional period allowed the fullest possible opportunity for public comment and receipt of new data to upgrade the status of these ingredients.

As mentioned, no substantive comments or new data were submitted to support reclassification of any of these active ingredients to monograph status. Therefore, before a final rule on each respective drug category is published, the Commissioner has determined that these ingredients are not generally recognized as safe and effective and that any OTC drug product containing any of these active ingredients not be allowed to continue to be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. FDA has elected to act on these ingredients in advance of finalization of other monograph conditions in order to expedite completion of the OTC drug review. Table I below lists the title, docket number, and active ingredients of the specific rulemakings that are addressed in this final rule.

FDA advises that the active ingredients listed in this final rule will not be included in the relevant final monographs because they have not been shown to be generally recognized as safe and effective for their intended use. The agency is amending 21 CFR part 310 to list all of the active ingredients covered by this final rule by adding them to § 310.545 (21 CFR 310.545). The agency further advises that these active ingredients should be eliminated from OTC drug products by November 10, 1993, regardless of whether further testing is undertaken to justify future use, and regardless of whether the relevant OTC drug monographs have been finalized at that time. Therefore, on or after November 10, 1993, no OTC drug product containing any ingredient listed in this final rule and included in § 310.545 either labeled or intended as an active ingredient for the uses specified in that section may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product containing an ingredient subject to this final rule that is repackaged or relabeled after the effective date of this final rule must be in compliance with the final rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are urged to comply voluntarily with this final rule at the earliest possible date.

The agency points out that publication of this final rule does not preclude a manufacturer's testing an ingredient. New, relevant data can be submitted to the agency at a later date as the subject of an application that may provide for prescription or OTC marketing status. (See 21 CFR part 314.) As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in an appropriate citizen petition to amend or establish a monograph, as appropriate. (See § 10.30 (21 CFR 10.30).) However, marketing of products containing these active ingredients may not continue while the data are being evaluated by the agency.

In response to the proposed rule on certain additional OTC Category II and III ingredients, nine drug manufacturers and six consumers submitted comments. Copies of the comments received are on public display in the Dockets Management Branch (HFA-305), Food and Drug Adminstration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

1. One comment requested clarification of the statement that any product containing any of the listed ingredients and labeled for an OTC use as identified by the proposed rule will be considered nonmonograph and misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) (57 FR 38568 at 38572). The comment contended that this statement is limited in effect to the use of a listed ingredient as an active ingredient for the specified indication(s). Accordingly, this proposal does not extend to additional uses of the listed active ingredients covered by other OTC drug rulemaking proceedings.

The comment is correct. This final rule affects only the use of the listed ingredients as active ingredients for the specific indications under which they are listed. As stated in § 310.545, this rule is limited to "active ingredients" for various uses for which "* * * based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses: * * *."

2. One comment requested clarification of the agency's statement that "FDA has determined that the presence of these ingredients in an OTC drug product would result in that drug product not being generally recognized as safe and effective or would result in misbranding." (57 FR 38568). The comment contended that this statement applies only to the use of nonmonograph ingredients as active ingredients. The comment stated that certain nonmonograph ingredients may be used as inactive ingredients in product formulations, which should not cause the product to be misbranded, provided that no drug claims are made.

The agency's statement was made in the context of considering the affected ingredients as active ingredients. This final rule applies only to the use of the listed ingredients as active ingredients for the specific indications listed. The agency recognizes that some of the ingredients included in this final rule have valid uses as inactive ingredients (e.g., cinnamon oil, peppermint). Any inactive ingredient present in the product should have an appropriate purpose and be safe and suitable for use in the product in accordance with § 330.1(e) (21 CFR 330.1(e)). The presence of an appropriate inactive ingredient § 330.1(e) in a product will not cause the product to be misbranded, provided that no drug claims are attributed to the ingredient.

3. One comment requested that the proposed prohibition of salicylic acid in OTC topical antifungal drug products be expressly limited to its use as an active ingredient and not include its use as an adjuvant keratolytic in these drug products. The comment stated that following publication of the tentative final monograph for OTC topical antifungal drug products, additional data (Ref. 1) were submitted to that rulemaking on November 30, 1990, in support of salicylic acid as an adjuvant keratolytic in topical antifungal drug products. The comment stated that the criteria upon which the August 25, 1992, proposed rule is based are consonant with the characterization by agency personnel of the rulemaking as "administrative house cleaning" of ingredients no one is interested in. The comment contended that, from the standpoint of administrative procedural requirements, the criteria used by the agency to determine that an ingredient has been "abandoned" have not been met for salicylic acid as an adjuvant keratolytic.

The agency acknowledges that a submission of data was made on November 30, 1990. The agency reviewed that submission and informed the manufacturer in a letter dated February 15, 1991 (Ref. 2), that the "open, uncontrolled clinical trial does not provide any useful information." There were major flaws in the design of the clinical study. The agency stated in the August 25, 1992, proposal that no "substantive" comments or new data were submitted for the listed ingredients. The agency did not consider the November 30, 1990, data submission to be substantive. No other data were submitted to support monograph status for salicylic acid used as an adjuvant keratolytic in OTC topical antifungal drug products. Accordingly, the final rule does not contain an express limitation as requested by the comment.

References

(1) Comment No. C30, Docket No. 80N-0476, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to Guido Mendoza, Kramer Laboratories, Inc., coded LET24, Docket No. 80N-0476, Dockets Management Branch.

4. One comment requested that the agency delay its proposed action regarding benzoic acid and salicylic acid as active ingredients in OTC topical antifungal drug products. The comment acknowledged that substantive comments or adequate data have not been submitted to support benzoic acid and salicylic acid as Category I active ingredients for topical antifungal use. However, the comment stated that products containing these ingredients and labeled for the treatment of athletes foot and ringworm have been continuously marketed since 1932. The comment requested additional time to submit documentation and for an oral hearing.

Another comment requested that salsalate, an internal analgesic, antipyretic, and antirheumatic ingredient, be kept in Category III pending new studies and testing planned to be submitted before the final monograph. The comment stated that these studies would provide additional evidence of salsalate's OTC safety and efficacy.

The agency clearly stated in the proposal that "This proposal does not constitute a reopening of the administrative record or an opportunity to submit new data to any of the specified rulemakings." (57 FR 38568). In addition, § 330.10(a)(7)(v) (21 CFR 330.10(a)(7)(v)) of the regulations governing the OTC drug review states that new data and information submitted after the closing of the administrative record for a tentative final rule "* * * but prior to the establishment of a final monograph will be considered as a petition to amend the monograph and will be considered by the Commissioner only after a final monograph has been published in the **Federal Register** unless the Commissioner finds that good cause has been shown that warrants earlier consideration."

None of the comments offered good cause why the requested ingredients should not be included in this final rule. Benzoic acid and salicylic acid have been under consideration in the rulemaking for OTC topical antifungal drug products since 1974. The comment did not provide any explanation why data or comments were not submitted before the close of the administrative record on February 12, 1991. Salsalate has been under consideration in the rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products since 1972. The comment did not provide any explanation why the data were not submitted before the close of the administrative record on January 16, 1990. The appropriate course of action for both comments is to submit any new data to the specific rulemaking for that class of OTC drug products, in a citizen petition under §§ 10.30 and 330.10.

5. Seven comments objected to the proposed rulemaking as a ban on vitamin, mineral, and other natural food supplements. The comments were concerned that many nutritional supplements and herbs would be removed from the marketplace. One comment contended that a number of the ingredients (pyridoxine hydrochloride, betaine hycrochloride, papaya, capsicum, eucalyptus oil, hydrogen peroxide, calcium pantothenate, and riboflavin) have nutritional value. Two of the comments contended that the agency is ignoring the Proxmire Act of 1976 that instructed FDA to set up separate guidelines for dietary supplements.

The agency recognizes that some of the ingredients included in this rulemaking are also marketed as vitamins, minerals, and food supplements. This rule affects only the marketing of ingredients listed as active ingredients in specific types of OTC drug products for which unproven medical claims are being made. This rule does not affect the continued use and marketing of these ingredients in vitamin, mineral, and food supplement products and, thus, is in conformance with the 1976 amendment to the act (21 U.S.C. 350). The agency believes that the comments misinterpreted the agency's intent as a ban on the substance itself rather than a restriction on marketing ingredients with claims as an active ingredient for specific listed drug indications.

6. Three comments disagreed with the proposed listing of aspergillus oryza enzymes under digestive aid drug products in § 310.545(a)(8)(ii). One comment stated that the term describes a group of functionally different enzymes derived from a particular source. Another comment mentioned that there is no evidence that "aspergillus oryza enzymes" have been used in OTC drug products in the past or at the present time, and that inclusion in the listing appears inappropriate. Several comments stated that new information on lactase enzyme derived from *Aspergillus oryzae (A. oryzae)* had been submitted to the administrative record in the rulemaking for OTC digestive aid drug products. Thus, the comments contended that aspergillus oryza enzymes should be deleted from the list of nonmonograph ingredients until the digestive aid drug products rulemaking is completed, or if retained in the list, the agency should clarify that it does not include lactase enzyme derived from *A. oryzae*.

Aspergillus oryza enzymes were included in the listing in proposed § 310.545(a)(8)(ii) based on their listing in a call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179), and the Panel's statement that it was neither able to locate nor was it aware of any significant body of data demonstrating the safety and effectiveness of aspergillus oryza enzymes for treating the symptoms of intestinal distress (47 FR 454 at 458, January 5, 1982). As one comment noted, the term describes a group of functionally different enzymes derived from a particular source. Lactase enzyme is the only enzyme derived from *A. oryzae* for which the agency has received any data in the rulemaking for OTC digestive aid drug products. The comments are correct in stating that this particular enzyme should be excluded from this final rule. Accordingly, the agency is including a parenthetical phrase in the regulation following aspergillus oryza enzymes that states: "(except lactase enzymes derived from *Aspergillus oryzae*)."

7. One comment requested clarification of the status of camphor and menthol as external analgesic, anesthetic, and antipruritic active ingredients in fever blister and cold sore treatment drug products because of the listing of these ingredients in proposed § 310.545(a)(10)(v).

The proposed rule for OTC external analgesic fever blister and cold sore treatment drug products (55 FR 3370 at 3382 and 3383, January 31, 1990) provides that products containing ingredients listed in § 348.10(a) or (b) or combinations of ingredients identified in § 348.20(a)(1) or (a)(3) may be labeled "for * * * pain and itching associated with fever blisters and cold sores." Proposed § 348.10(b)(2) and (b)(6) of the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5867, February 8, 1983) list camphor at 0.1 to 3 percent and menthol at 0.1 to 1 percent, respectively. Camphor and menthol are also listed in § 348.12(b)(1) and (b)(2) at higher concentrations for counterirritant use.

The August 25, 1992 proposed rule that listed camphor and menthol in § 310.545(a)(10)(v) was intended to apply to the higher (counterirritant) concentrations of camphor and menthol only. The agency is clarifying this fact in this final rule by adding in § 310.545(a)(10)(v) the parenthetical phrase "(exceeding 3 percent)" after the entry for camphor and by adding the parenthetical phrase "(exceeding 1 percent)" after the entry for menthol.

II. Summary of Significant Changes From the Proposed Rule

1. The agency is including a parenthetical phrase following aspergillus oryza enzymes in § 310.545(a)(8)(ii) that states: "(except lactase enzymes derived from *Aspergillus oryzae*)." (See comment 6.)

2. The agency is adding in § 310.545(a)(10)(v) the parenthetical phrase "(exceeding 3 percent)" after the entry for camphor and adding the parenthetical phrase "(exceeding 1 percent)" after the entry for menthol. (See comment 7.)

3. The agency is redesignating several of the proposed paragraphs in § 310.545 of this final rule as follows:

Proposed rule	Final rule
(a)(21)(i)	(a)(22)(ii)
(a)(22) through (a)(24).	(a)(23) through (a)(25)
(d)(4)	(d)(11)

III. The Agency's Final Conclusions on Certain Additional OTC Drug Category II and III Active Ingredients

The agency has determined that no substantive comments or additional data have been submitted to the OTC drug review to support any of the ingredients listed below as being generally recognized as safe and effective for the OTC drug uses specified in the table (Table I). Based on the agency's procedural regulations (21 CFR 330.10(a)(7)(ii)), the agency has determined that these ingredients are not generally recognized as safe and effective and are misbranded when present in the following specific OTC drug products:

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE

Rulemaking
(1) Digestive Aid Drug Products (Docket No. 81N–0106):
Alcohol
Aluminum hydroxide
Amylase
Anise seed
Aromatic powder
Asafetida
Aspergillus oryza enzymes (except lactase enzyme derived from *Aspergillus oryzae*)
Bacillus acidophilus
Bean
Belladonna alkaloids
Belladonna leaves, powdered extract
Betaine hydrochloride
Bismuth subcarbonate
Bismuth subgallate
Black radish powder
Blessed thistle (cnicus benedictus)
Buckthorn
Calcium gluconate
Capsicum
Capsicum, fluid extract of
Carbon
Cascara sagrada extract
Catechu, tincture
Catnip
Chamomile flowers
Charcoal, wood
Chloroform
Cinnamon oil
Cinnamon tincture
Citrus pectin
Diastase
Diastase malt
Dog grass
Elecampane
Ether
Fennel acid
Galega
Ginger
Glycine
Hydrastis canadensis (golden seal)
Hectorite
Horsetail
Huckleberry
Hydrastis fluid extract
Hydrochloric acid
Iodine
Iron ox bile
Johnswort
Juniper
Kaolin, colloidal
Knotgrass

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking
Lactic acid
Lactose
Lavender compound, tincture of
Linden
Lipase
Lysine hydrochloride
Mannitol
Mycozyme
Myrrh, fluid extract of
Nettle
Nickel-pectin
Nux vomica extract
Orthophosphoric acid
Papaya, natural
Pectin
Peppermint
Peppermint spirit
Phenacetin
Potassium bicarbonate
Potassium carbonate
Protease
Prolase
Rhubarb fluid extract
Senna
Sodium chloride
Sodium salicylate
Stem bromelain
Strawberry
Strychnine
Tannic acid
Trillium
Woodruff
(2) External Analgesic Drug Products:
(a) Fever Blister and Cold Sore Treatment Drug Products (Docket No. 78N–301F):
Allyl isothiocyanate
Aspirin
Bismuth sodium tartrate
Camphor (exceeding 3 percent)
Capsaicin
Capsicum
Capsicum oleoresin
Chloral hydrate
Chlorobutanol
Cyclomethycaine sulfate
Eucalyptus oil
Eugenol
Glycol salicylate
Hexylresorcinol
Histamine dihydrochloride
Menthol (exceeding 1 percent)
Methapyrilene hydrochloride
Methyl nicotinate
Methyl salicylate
Pectin
Salicylamide
Strong ammonia solution
Tannic acid
Thymol
Tripelennamine hydrochloride
Trolamine salicylate
Turpentine oil
Zinc sulfate
(b) Insect Bite and Sting Drug Products (Docket No. 78N–301P):
Alcohol
Alcohol, ethoxylated alkyl
Benzalkonium chloride

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking
Calamine
Ergot fluidextract
Ferric chloride
Panthenol
Peppermint oil
Pyrilamine maleate
Sodium borate
Trolamine salicylate
Turpentine oil
Zinc oxide
Zirconium oxide
(c) Poison Ivy, Poison Oak, and Poison Sumac Drug Products (Docket No. 78N–301P):
Alcohol
Aspirin
Benzethonium chloride
Benzocaine (0.5 to 1.25 percent)
Bithionol
Calamine
Cetalkonium chloride
Chloral hydrate
Chlorobutanol
Chlorpheniramine maleate
Creosote, beechwood
Cyclomethycaine sulfate
Dexpanthenol
Diperodon hydrochloride
Eucalyptus oil
Eugenol
Glycerin
Glycol salicylate
Hectorite
Hexylresorcinol
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Merbromin
Mercuric chloride
Methapyrilene hydrochloride
Panthenol
Parethoxycaine hydrochloride
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Pyrilamine maleate
Salicylamide
Salicylic acid
Simethicone
Sulfur
Tannic acid
Thymol
Trolamine salicylate
Turpentine oil
Zirconium oxide
Zyloxin
(3) Skin Protectant Drug Products:
(a) Astringent Drug Products (Docket No. 78N–021A):
Acetone
Alcohol
Alum, ammonium
Alum, potassium
Aluminum chlorhydroxy complex
Aromatics
Benzalkonium chloride

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued
TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking
Benzethonium chloride
Benzocaine
Benzoic acid
Boric acid
Calcium acetate
Camphor gum
Clove oil
Colloidal oatmeal
Cresol
Cupric sulfate
Eucalyptus oil
Eugenol
Honey
Isopropyl alcohol
Menthol
Methyl salicylate
Oxyquinoline sulfate
P-t-butyl-m-cresol
Peppermint oil
Phenol
Polyoxyethylene laurate
Potassium ferrocyanide
Sage oil
Silver nitrate
Sodium borate
Sodium diacetate
Talc
Tannic acid glycerite
Thymol
Topical starch
Zinc chloride
Zinc oxide
Zinc phenolsulfonate
Zinc stearate
Zinc sulfate
(b) Diaper Rash Drug Products (Docket No. 78N–021D):
Aluminum hydroxide
Cocoa butter
Cysteine hydrochloride
Glycerin
Protein hydrolysate
Racemethionine
Sulfur
Tannic acid
Zinc acetate
Zinc carbonate
(c) Fever Blister and Cold Sore Treatment Drug Products (Docket No. 78N–021F):
Bismuth subnitrate
Boric acid
Pyridoxide hydrochloride
Sulfur
Tannic acid
Topical starch
Trolamine
Zinc sulfate
(d) Insect Bite and Sting Drug Products (Docket No. 78N–021P):
Alcohol
Alcohol, ethoxylated alkyl
Ammonia solution, strong
Ammonium hydroxide
Benzalkonium chloride
Camphor
Ergot fluidextract
Ferric chloride
Menthol
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Trolamine
Turpentine oil
Zirconium oxide
(e) Poison Ivy, Poison Oak, and Poison Sumac Drug Products (Docket No. 78N–021P):
Alcohol
Anion and cation exchange resins buffered
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bismuth subnitrate
Bithionol
Boric acid
Camphor
Cetalkonium chloride
Chloral hydrate
Chlorpheniramine maleate
Creosote
Diperodon hydrochloride
Diphenhydramine hydrochloride
Eucalyptus oil
Ferric chloride
Glycerin
Hectorite
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride
Panthenol
Parethoxycaine hydrochloride
Phenol
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Salicylic acid
Simethicone
Tannic acid
Topical starch
Trolamine
Turpentine oil
Zirconium oxide
Zyloxin
(4) Topical Antifungal Drug Products (Docket No. 80N–0476):
Alcloxa
Alum, potassium
Aluminum sulfate
Amyltricresols, secondary
Basic fuchsin
Benzethonium chloride
Benzoic acid
Benzoxiquine
Boric acid
Camphor
Candicidin
Chlorothymol
Coal tar
Dichlorophen
Menthol
Methylparaben
Oxyquinoline
Oxyquinoline sulfate
Phenol
Phenolate sodium
Phenyl salicylate
Propionic acid
Propylparaben
Resorcinol
Salicylic acid
Sodium borate
Sodium caprylate
Sodium propionate
Sulfur
Tannic acid
Thymol
Tolindate
Triacetin
Zinc caprylate
Zinc propionate
(5) Internal Analgesic Drug Products (Docket No. 77N–0094):
Aminobenzoic acid[1]
Antipyrine
Aspirin, aluminum
Calcium salicylate
Codeine
Codeine phosphate
Codeine sulfate
Iodoantipyrine
Lysine aspirin
Methapyrilene fumarate[1]
Phenacetin
Pheniramine maleate[1]
Pyrilamine maleate[1]
Quinine
Salsalate
Sodium aminobenzoate[1]
(6) Orally Administered Menstrual Drug Products (Docket No. 82N–0165):
Alcohol
Alfalfa leaves
Aloes
Asclepias tuberosa
Asparagus
Barosma
Bearberry (extract of uva ursi)
Bearberry fluidextract (extract of bearberry)
Blessed thistle (cnicus benedictus)
Buchu powdered extract (extract of buchu)
Calcium lactate
Calcium pantothenate
Capsicum oleoresin
Cascara fluidextract, aromatic (extract of cascara)
Chlorprophenpyridamine maleate
Cimicifuga racemosa
Codeine
Collinsonia (extract stone root)
Corn silk
Couch grass
Dog grass extract
Ethyl nitrite
Ferric chloride

TABLE I.—OTC DRUG RULEMAKINGS AND ACTIVE INGREDIENTS COVERED BY THIS NOTICE—Continued

Rulemaking
Ferrous sulfate
Gentiana lutea (gentian)
Glycyrrhiza (licorice)
Homatropine methylbromide
Hydrangea, powdered extract (extract of hydrangea)
Hydrastis canadensis (golden seal)
Hyoscyamine sulfate
Juniper oil (oil of juniper)
Magnesium sulfate
Methapyrilene hydrochloride
Methenamine
Methylene blue
Natural estrogenic hormone
Niacinamide
Nutmeg oil (oil of nutmeg)
Oil of erigeron
Parsley
Peppermint spirit
Pepsin, essence
Phenacetin
Phenindamine tartrate
Phenyl salicylate
Piscidia erythrina
Pipsissewa
Potassium acetate
Potassium nitrate
Riboflavin
Saw palmetto
Senecio aureus
Sodium benzoate
Sodium nitrate
Sucrose
Sulferated oils of turpentine
Taraxacum officinale
Theobromine sodium salicylate
Theophylline
Thiamine hydrochloride
Triticum
Turpentine, venice (venice turpentine)
Urea
(7) Pediculicide Drug Products (Docket No. 81N-0201):
Benzocaine
Benzyl alcohol
Benzyl benzoate
Chlorophenothane (dichlorodiphenyl trichloroethane)
Coconut oil soap, aqueous
Copper oleate
Docusate sodium
Formic acid[2]
Isobornyl thiocyanoacetate
Picrotoxin
Propylene glycol
Sabadilla alkaloids
Sulfur, sublimed
Thiocyanoacetate

[1] Ingredient used as an analgesic-antipyretic adjuvant.
[2] This ingredient was not submitted to or previously classified in the OTC drug review, but has been observed in a marketed product.

Accordingly, any drug product containing any of these ingredients either labeled or intended as an active ingredient for any of the OTC uses identified above will be considered nonmonograph and misbranded under section 502 of the act (21 U.S.C. 352) and a new drug under section 201(p) of the act (21 U.S.C. 321(p)) for which an approved application or abbreviated application under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 of the regulations is required for marketing. As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in a citizen petition to amend the appropriate monograph to include any of the above active ingredients in OTC drug products. (See 21 CFR 10.30.)

Any OTC drug product containing any of the above ingredients either labeled or intended as an active ingredient for the uses included in the above rulemakings that is initially introduced or initially delivered for introduction into interstate commerce after November 10, 1993 and that is not the subject of an approved application or abbreviated application will be in violation of sections 502 and 505 of the act (21 U.S.C. 352 and 355) and, therefore, subject to regulatory action. Further, any OTC drug product containing an ingredient subject to this rulemaking that is repackaged or relabeled after November 10, 1993 must be in compliance with the rule regardless of the date the product was initially introduced or intitially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (57 FR 38568 at 38572). The agency concludes that there is no basis for the continued marketing of these ingredients for the uses listed in Table I above. There are other ingredients being considered for monograph status that manufacturers can use to reformulate affected products. In many instances, manufacturers have already reformulated their products to include these ingredients. As a result of this final rule, manufacturers may need to reformulate some products prior to promulgation of the applicable final monograph. However, there will be no additional costs because reformulation would be required, in any event, when the final monograph is published.

Early finalization of the nonmonograph status of the ingredients listed in this notice will benefit both consumers and manufacturers. Consumers will benefit from the early removal from the marketplace of ingredients for which safety and effectiveness have not been established. This action will result in a direct economic savings to consumers. Manufacturers will benefit from being able to use alternative ingredients that are under review to determine general recognition of safety and effectiveness, without incurring additional expense of clinical testing for these ingredients. Based on the above, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, 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 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

2. Section 310.545 is amended by redesignating the text of paragraphs (a)(8) and (a)(18) as paragraphs (a)(8)(i) and (a)(18)(i), respectively; by adding new (a)(8)(i) heading, (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(i) heading, (a)(18)(ii) through (a)(18)(vi), (a)(22)(ii), (a)(23) through (a)(25), and (d)(11); and by revising paragraph (d) introductory text and paragraph (d)(1) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(8) *Digestive aid drug products*—(i) *Approved as of May 7, 1991.* * * *

(ii) *Approved as of November 10, 1993.*

Alcohol
Aluminum hydroxide

Amylase
Anise seed
Aromatic powder
Asafetida
Aspergillus oryza enzymes (except lactase enzyme derived from *Aspergillus oryzae*)
Bacillus acidophilus
Bean
Belladonna alkaloids
Belladonna leaves, powdered extract
Betaine hydrochloride
Bismuth subcarbonate
Bismuth subgallate
Black radish powder
Blessed thistle (cnicus benedictus)
Buckthorn
Calcium gluconate
Capsicum
Capsicum, fluid extract of
Carbon
Cascara sagrada extract
Catechu, tincture
Catnip
Chamomile flowers
Charcoal, wood
Chloroform
Cinnamon oil
Cinnamon tincture
Citrus pectin
Diastase
Diastase malt
Dog grass
Elecampane
Ether
Fennel acid
Galega
Ginger
Glycine
Hydrastis canadensis (golden seal)
Hectorite
Horsetail
Huckleberry
Hydrastis fluid extract
Hydrochloric acid
Iodine
Iron ox bile
Johnswort
Juniper
Kaolin, colloidal
Knotgrass
Lactic acid
Lactose
Lavender compound, tincture of
Linden
Lipase
Lysine hydrochloride
Mannitol
Mycozyme
Myrrh, fluid extract of
Nettle
Nickel-pectin
Nux vomica extract
Orthophosphoric acid
Papaya, natural
Pectin
Peppermint
Peppermint spirit
Phenacetin
Potassium bicarbonate
Potassium carbonate
Protease
Prolase
Rhubarb fluid extract
Senna
Sodium chloride
Sodium salicylate
Stem bromelain
Strawberry
Strychnine
Tannic acid
Trillium
Woodruff

* * * * *

(10) * * *

(v) *Fever blister and cold sore treatment drug products.*

Allyl isothiocyanate
Aspirin
Bismuth sodium tartrate
Camphor (exceeding 3 percent)
Capsaicin
Capsicum
Capsicum oleoresin
Chloral hydrate
Chlorobutanol
Cyclomethycaine sulfate
Eucalyptus oil
Eugenol
Glycol salicylate
Hexylresorcinol
Histamine dihydrochloride
Menthol (exceeding 1 percent)
Methapyrilene hydrochloride
Methyl nicotinate
Methyl salicylate
Pectin
Salicylamide
Strong ammonia solution
Tannic acid
Thymol
Tripelennamine hydrochloride
Trolamine salicylate
Turpentine oil
Zinc sulfate

(vi) *Insect bite and sting drug products.*

Alcohol
Alcohol, ethoxylated alkyl
Benzalkonium chloride
Calamine
Ergot fluidextract
Ferric chloride
Panthenol
Peppermint oil
Pyrilamine maleate
Sodium borate
Trolamine salicylate
Turpentine oil
Zinc oxide
Zirconium oxide

(vii) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol
Aspirin
Benzethonium chloride
Benzocaine (0.5 to 1.25 percent)
Bithionol
Calamine
Cetalkonium chloride
Chloral hydrate
Chlorobutanol
Chlorpheniramine maleate
Creosote, beechwood
Cyclomethycaine sulfate
Dexpanthenol
Diperodon hydrochloride
Eucalyptus oil
Eugenol
Glycerin
Glycol salicylate
Hectorite
Hexylresorcinol
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Merbromin
Mercuric chloride
Methapyrilene hydrochloride
Panthenol
Parethoxycaine hydrochloride
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Pyrilamine maleate
Salicylamide
Salicylic acid
Simethicone
Sulfur
Tannic acid
Thymol
Trolamine salicylate
Turpentine oil
Zirconium oxide
Zyloxin

* * * * *

(18) *Skin protectant drug products*—(i) Ingredients. * * *

(ii) *Astringent drug products.*

Acetone
Alcohol
Alum, ammonium
Alum, potassium
Aluminum chlorhydroxy complex
Aromatics
Benzalkonium chloride
Benzethonium chloride
Benzocaine
Benzoic acid
Boric acid
Calcium acetate
Camphor gum
Clove oil
Colloidal oatmeal
Cresol
Cupric sulfate
Eucalyptus oil
Eugenol
Honey
Isopropyl alcohol
Menthol
Methyl salicylate
Oxyquinoline sulfate
P-t-butyl-m-cresol
Peppermint oil
Phenol
Polyoxeythylene laurate
Potassium ferrocyanide
Sage oil
Silver nitrate
Sodium borate
Sodium diacetate
Talc
Tannic acid glycerite
Thymol
Topical starch
Zinc chloride
Zinc oxide
Zinc phenolsulfonate
Zinc stearate
Zinc sulfate

(iii) *Diaper rash drug products.*

Aluminum hydroxide

Cocoa butter
Cysteine hydrochloride
Glycerin
Protein hydrolysate
Racemethionine
Sulfur
Tannic acid
Zinc acetate
Zinc carbonate

(iv) *Fever blister and cold sore treatment drug products.*

Bismuth subnitrate
Boric acid
Pyridoxine hydrochloride
Sulfur
Tannic acid
Topical starch
Trolamine
Zinc sulfate

(v) *Insect bite and sting drug products.*

Alcohol
Alcohol, ethoxylated alkyl
Ammonia solution, strong
Ammonium hydroxide
Benzalkonium chloride
Camphor
Ergot fluidextract
Ferric chloride
Menthol
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Trolamine
Turpentine oil
Zirconium oxide

(vi) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol
Anion and cation exchange resins buffered
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bismuth subnitrate
Bithionol
Boric acid
Camphor
Cetalkonium chloride
Chloral hydrate
Chlorpheniramine maleate
Creosote
Diperodon hydrochloride
Diphenhydramine hydrochloride
Eucalyptus oil
Ferric chloride
Glycerin
Hectorite
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride
Panthenol
Parethoxycaine hydrochloride
Phenol
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Salicylic acid
Simethicone
Tannic acid
Topical starch
Trolamine
Turpentine oil
Zirconium oxide
Zyloxin

* * * * *

(22) * * *

(ii) *Ingredients.*

Alcloxa
Alum, potassium
Aluminum sulfate
Amyltricresols, secondary
Basic fuchsin
Benzethonium chloride
Benzoic acid
Benzoxiquine
Boric acid
Camphor
Candicidin
Chlorothymol
Coal tar
Dichlorophen
Menthol
Methylparaben
Oxyquinoline
Oxyquinoline sulfate
Phenol
Phenolate sodium
Phenyl salicylate
Propionic acid
Propylparaben
Resorcinol
Salicylic acid
Sodium borate
Sodium caprylate
Sodium propionate
Sulfur
Tannic acid
Thymol
Tolindate
Triacetin
Zinc caprylate
Zinc propionate

(23) *Internal analgesic drug products.*

Aminobenzoic acid
Antipyrine
Aspirin, aluminum
Calcium salicylate
Codeine
Codeine phosphate
Codeine sulfate
Iodoantipyrine
Lysine aspirin
Methapyrilene fumarate
Phenacetin
Pheniramine maleate
Pyrilamine maleate
Quinine
Salsalate
Sodium aminobenzoate

(24) *Orally administered menstrual drug products.*

Alcohol
Alfalfa leaves
Aloes
Asclepias tuberosa
Asparagus
Barosma
Bearberry (extract of uva ursi)
Bearberry fluidextract (extract of bearberry)
Blessed thistle (cnicus benedictus)
Buchu powdered extract (extract of buchu)
Calcium lactate
Calcium pantothenate
Capsicum oleoresin
Cascara fluidextract, aromatic (extract of cascara)
Chlorprophenpyridamine maleate
Cimicifuga racemosa
Codeine
Collinsonia (extract stone root)
Corn silk
Couch grass
Dog grass extract
Ethyl nitrite
Ferric chloride
Ferrous sulfate
Gentiana lutea (gentian)
Glycyrrhiza (licorice)
Homatropine methylbromide
Hydrangea, powdered extract (extract of hydrangea)
Hydrastis canadensis (golden seal)
Hyoscyamine sulfate
Juniper oil (oil of juniper)
Magnesium sulfate
Methapyrilene hydrochloride
Methenamine
Methylene blue
Natural estrogenic hormone
Niacinamide
Nutmeg oil (oil of nutmeg)
Oil of erigeron
Parsley
Peppermint spirit
Pepsin, essence
Phenacetin
Phenindamine tartrate
Phenyl salicylate
Piscidia erythrina
Pipsissewa
Potassium acetate
Potassium nitrate
Riboflavin
Saw palmetto
Senecio aureus
Sodium benzoate
Sodium nitrate
Sucrose
Sulferated oils of turpentine
Taraxacum officinale
Theobromine sodium salicylate
Theophylline
Thiamine hydrochloride
Triticum
Turpentine, venice (venice turpertine)
Urea

(25) *Pediculicide drug products.*

Benzocaine
Benzyl alcohol
Benzyl benzoate
Chlorophenothane (dichlorodiphenyl trichloroethane)
Coconut oil soap, aqueous
Copper oleate
Docusate sodium
Formic acid
Isobornyl thiocyanoacetate
Picrotoxin
Propylene glycol
Sabadilla alkaloids
Sulfur, sublimed
Thiocyanoacetate

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(11) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(6)(i)(A), (a)(6)(ii), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(9) through (a)(10)(iii), (a)(11) through (a)(18)(i), and (a)(19) of this section.

* * * * *

(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) through (a)(18)(vi), (a)(22)(ii), and (a)(23) through (a)(25) of this section.

Dated: March 31, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-10958 Filed 5-7-93; 8:45 am]

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federal register

Monday
May 10, 1993

Part V

The President

Memorandum of May 6—Determination Under the Bus Regulatory Reform Act of 1982

Proclamation 6558—National Walking Week, 1993

Federal Register
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Presidential Documents

Title 3—

The President

Memorandum of May 6, 1993

Determination Under the Bus Regulatory Reform Act of 1982

Memorandum for the Secretary of Transportation

Section 6 of the Bus Regulatory Reform Act of 1982 imposed a moratorium on the issuance of certificates or permits to motor carriers domiciled in, or owned or controlled by persons of, a contiguous foreign country. The Act authorized the President to remove the moratorium in whole or in part for any country or political subdivision thereof upon determining that such action is in the national interest. Sixty days' advance notice to the Congress is required whenever the removal or modification applies to a contiguous foreign country or political subdivision thereof that substantially prohibits the granting of motor carrier authority to persons from the United States.

I am pleased that an agreement between the United States and Mexico has been concluded to ensure fair and reciprocal treatment for charter and tour bus interests on both sides of the border. The agreement reached, however, does not allow for full access to cross-border and domestic markets. Therefore, the moratorium must reflect the conditions under which operating authority may be issued to Mexican charter and tour companies under the agreement.

Pursuant to section 6 of the Bus Regulatory Reform Act of 1982, 49 U.S.C. section 10922(*l*)(2)(A), I hereby make a limited modification to the moratorium imposed by that section and all actions taken by my predecessors under that section on the issuance of certificates or permits to motor carriers domiciled in, or owned or controlled by persons of, a contiguous foreign country.

The moratorium is modified only to authorize the Interstate Commerce Commission to grant Mexican motor carriers authority to transport passengers in charter or special operations, in foreign commerce, in round trip or one-way service between Mexico and the United States pursuant to the following restrictions:

1. The Mexican motor carrier can conduct cross-border charter or special service in the United States only when the international tour or charter begins in Mexico;

2. Tickets or tour packages for such operations cannot be sold in the United States; and

3. The terms of the grants of authority given to Mexican motor carriers will be limited by the life of the agreement with Mexico covering reciprocal cross-border charter and special operations.

This action applies only to international charter and tour operations, does not allow for point-to-point service within the United States, and does not authorize companies to conduct cross-border regular route service. This action preserves the status quo with respect to Mexican trucking companies and Mexican companies engaged in regular route service, and will maintain the moratorium on those operations through September 25, 1994, unless earlier revoked or modified.

Accordingly, you are directed to notify the Congress today on my behalf that, effective 60 days hence, the moratorium will no longer be in effect for Mexican charter and tour bus companies subject to the above stated conditions. Because of this action, the Interstate Commerce Commission will then accept and process expeditiously all applications for operating authority from Mexican owned, controlled, or domiciled charter and tour bus firms. I should note that applications in Mexico by United States charter and tour bus firms will be similarly treated.

You are hereby authorized and directed to publish this determination in the Federal Register.

William J. Clinton

THE WHITE HOUSE,
Washington, May 6, 1993.

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