The agency estimates the range of reformulation costs is from $100,000 to $500,000 per product. As most affected firms have only one or two products containing these ingredients, the midpoint of the cost estimate for reformulation implies total costs of $300,000 to $600,000 per firm. If all manufacturers decide to reformulate, about 56 products would be affected. Using the midpoint of the estimated cost to reformulate ($300,000) implies total costs of $16.8 million. However, the agency believes the total costs will be lower because not all firms will choose to reformulate. Some firms may choose to discontinue a product line if sales are too low to justify the added cost of reformulation and/or they may place their market emphasis on other OTC laxative drug products. The lost sales from the products containing nonmonograph ingredients may be offset by sales of the substitute products containing monograph ingredients. In addition, firms have been aware of the proposed nonmonograph status of these products since 1998 and have not submitted data to the agency. While this final rule may cause firms to discontinue marketing or to reformulate some products prior to issuance of the final monograph, these firms have known for some time that if adequate data were not submitted to support safety, cessation of marketing of the current products would be required, in any event, when the final monograph is published.

The agency estimates that the average cost to relabel OTC drug products is about $3,600. The agency is unsure of how many products will require new labeling. If all of the 170 products are reformulated and are still marketed, then the one-time costs to relabel would be $612,000. The estimated total one-time reformulation and relabeling cost would be $17.8 million.

The agency considered but rejected not acting on these ingredients in advance of the finalization of other monograph conditions. As firms have not submitted the requested safety data, these ingredients will not be included in the final monograph when completed. The agency has determined that there is no reason to allow continued marketing of OTC laxative drug products containing any of these ingredients. Consumers will benefit from the early removal from the marketplace of products containing ingredients for which safety has not been established. Consumers can then purchase products containing only ingredients proposed for monograph status. Manufacturers who choose to reformulate or replace affected products will be able to use alternate ingredients, as discussed previously in this document, that are proposed as monograph conditions without incurring any additional expense of clinical testing for those ingredients.

Because these products must be manufactured in compliance with the pharmaceutical current good manufacturing practices (parts 210 and 211), all firms have the necessary skills and personnel to perform the tasks of reformulation, validation, and relabeling either in-house or by contractual arrangement. No additional professional skills are needed. No other Federal rules duplicate, overlap, or conflict with this rule.

The agency has considered the burden to small entities and identified reformulation options available to them. Nevertheless, some entities may incur significant impacts, especially private label manufacturers that provide labeling for a number of the affected products. This economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

IV. Paperwork Reduction Act of 1995

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

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

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: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by adding paragraphs (a)(12)(iv)(C) and (d)(30) to read as follows:

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

(a) * * *

(12) * * *

(iv)(C) *Stimulant laxatives—Approved as of* November 5, 2002.

Aloe ingredients (aloe, aloe extract, aloe flower extract)

Cascara sagrada ingredients (casanthranol, cascara fluidextract aromatic, cascara sagrada bark, cascara sagrada extract, cascara sagrada fluidextract).

* * * * *

(d) * * *

(30) November 5, 2002, for products subject to paragraph (a)(12)(iv)(C) of this section.

* * * * *

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–11510 Filed 5–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 286

DoD Freedom of Information Act (FOIA) Program

AGENCY: Department of Defense.

ACTION: Final rule; amendment.

SUMMARY: The search and review rates for processing Freedom of Information Act (FOIA) requests within the Department of Defense are being increased at the recommendation of the General Accounting Office (GAO). FOIA

requesters will incur more direct costs for search and review, if applicable.

DATES: This rule is effective July 1, 2002.

FOR FURTHER INFORMATION CONTACT: D. Maier, (703) 697–1160.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 286

Freedom of Information.

Accordingly, 32 CFR part 286 is amended as follows:

PART 286—DOD FREEDOM OF INFORMATION ACT PROGRAM REGULATION

1. The authority citation continues to read as follows:

Authority: 5 U.S.C. 552.

2. In § 286.29, the tables in paragraphs (b)(1) and (d) are revised to read as follows:

§ 286.29 Collection of fees and fee rates.

* * * * *

(b) * * *

(1) * * *

Type	Grade	Hourly Rate
Clerical	E1–E9/GS1–GS8.	$20.00
Professional ...	O1–O6/GS9–GS15.	44.00
Executive	ES1–ES6/O7–O10.	75.00
Contractor	.....	44.00

* * * * *

(d) * * *

Type	Grade	Hourly Rate
Clerical	E1–E9/GS1–GS8.	$20.00
Professional ...	O1–O6/GS9–GS15.	44.00
Executive	ES1–ES6/O7–O10.	75.00
Contractor	.....	44.00

* * * * *

Dated: May 1, 2002.

Patricia Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 02–11381 Filed 5–8–02; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07–01–048]

RIN 2115–AA97

Security Zone; St. Croix, U.S. Virgin Islands

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the security zones around commercial tank and freight vessels moored at the HOVENSA facility in St. Croix, U.S. Virgin Islands. The zones were created for national security reasons and to protect the public and port of Limetree Bay (HOVENSA) from subversive acts. The zone is no longer needed because the HOVENSA facility has upgraded security measures, installed controlled access points and implemented internal security procedures for permitting crewmembers to leave vessels moored at their facility.

DATES: Temporary § 165.T07–002 is removed effective May 9, 2002.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket [CGD07–01–048] and are available for inspection or copying at Marine Safety Office San Juan, San Martin Street #90, RODVAl Building, Suite 400, Guaynabo, PR 00968 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Robert Lefevers, U.S. Coast Guard Marine Safety Office, San Juan, Puerto Rico, (787) 706–2444.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that publishing an NPRM is unnecessary because this rule removes temporary security zones that are no longer needed because the HOVENSA facility has implemented internal security procedures for deciding which crewmembers are permitted to leave their vessels and enter the facility's property. For the same burden-lifting reason, under 5 U.S.C. 553(d)(3), we find good cause exists to make this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

On September 28, 2001, the first in a series of temporary rules creating security zones around commercial tank and freight vessels moored at the HOVENSA facility in St. Croix, U.S. Virgin Islands was published in the **Federal Register** (66 FR 49534). The zones created by that first rule were scheduled to terminate October 15, 2001, but they were revived twice—by a temporary rule issued in October 2001 (that was sent to Washington, D.C. for publication in the **Federal Register** but that was delayed in the mail [CGD07–01–125; 67 FR 9194, 9197, February 28, 2002]), and another issued in January 2002 (67 FR 4911, February 1, 2002).

When it was issued, the current temporary rule that created temporary section 165.T07–002 of Title 33 of the Code of Federal Regulations, was scheduled to expire on June 15, 2002. Temporary section 165.T07–002 requires all persons aboard commercial tank and freight vessels to remain onboard when moored at the HOVENSA facility in St. Croix, U.S. Virgin Islands unless they have permission from the Captain of the Port to transit the security zone around the vessel.

These security zones were needed to prevent subversive acts and to protect the public and the port of HOVENSA. The security zones are no longer needed because HOVENSA has implemented internal security procedures for deciding which persons can depart the vessels moored at their facility. Therefore, the Coast Guard is removing this security zone regulation effective May 9, 2002.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.