record would not be preserved). The ability to overwrite or erase records stored on these systems makes them non-compliant with Rule 17a–4(f).

Any system used by a broker-dealer must comply with every requirement in paragraph (f) of the rule. Among other requirements in paragraph (f), the broker-dealer would need to have in place an audit system providing for accountability regarding the inputting of records into the storage system.[13] The audit procedures for a storage system using integrated software and hardware codes to comply with paragraph (f) would need to provide accountability regarding the length of time records are stored in a non-rewriteable and non-erasable manner. This should include senior management level approval of how the system is configured to store records for their required retention periods in a non-rewriteable and non-erasable manner. It would be prudent to configure such a storage system so that records input without an expiry or a retention period, by default, would be assigned a permanent retention period. This would help to ensure the records are maintained in accordance with the retention periods specified in Rule 17a–4 or other applicable Commission rules.

Moreover, there may be circumstances (such as receipt of a subpoena) where a broker-dealer is required to maintain records beyond the retention periods specified in Rule 17a–4 or other applicable Commission rules. Accordingly, a broker-dealer must take appropriate steps to ensure that records are not deleted during periods when the regulatory retention period has lapsed but other legal requirements mandate that the records continue to be maintained, and the broker-dealer's storage system must allow records to be retained beyond the retentions periods specified in Commission rules.

V. Conclusion

For the foregoing reasons, the Commission finds this interpretation to be consistent with section 17 of the Exchange Act and Rule 17a–4 thereunder.

List of Subjects in 17 CFR Part 241

Securities.

Amendment to the Code of Federal Regulations

■ For the reasons set out in the preamble, the Commission is amending title 17, chapter II of the Code of Federal Regulations as set forth below:

[13] 17 CFR 240.17a–4(f)(3)(v).

PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

■ Part 241 is amended by adding Release No. 34–47806 and the release date of May 7, 2003 to the list of interpretive releases.

By the Commission.

Dated: May 7, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–11727 Filed 5–9–03; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, 20, 314, and 720

[Docket No. 99N–2637]

Public Information Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations to comply with the requirements of the Electronic Freedom of Information Amendments of 1996 (EFOIA). EFOIA is designed to broaden public access to Government documents by making them more accessible in electronic form and by streamlining the process by which agencies generally disclose information.

DATES: This rule is effective July 28, 2003.

FOR FURTHER INFORMATION CONTACT: Betty Dorsey, Freedom of Information Staff (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6567.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 4, 1999 (64 FR 60143), FDA published a proposed rule that would amend its public information regulations in part 20 (21 CFR part 20) to comply with the requirements of the EFOIA and to clarify and update certain provisions unrelated to EFOIA. EFOIA authorizes, and in some instances requires, agencies to issue regulations implementing certain of its provisions, including provisions regarding the aggregation of Freedom of Information Act (FOIA) requests, the expedited processing of FOIA requests, and the establishment of separate queues for the processing of FOIA requests. In addition, EFOIA amends the time limits for responding to an FOIA request from 10 to 20 working days, the process by which an agency may extend the time for responding to an FOIA request, and the requirements for reporting on FOIA activities. EFOIA also includes provisions regarding the availability of records in electronic form, the establishment of ''electronic reading rooms,'' and provisions requiring agencies to inform requesters about the amount of information not being released to them.

In addition to the changes in the proposed rule, this document also reflects technical changes caused by the redesignation of several provisions and by the revocation of existing § 20.44 for the reasons outlined in the proposed rule.

II. Discussion of Comments on the Proposed Rule

FDA received one comment on the proposed rule from a pharmaceutical research and development organization.

A. Section 20.33—Form or Format of Response

The proposal would revise the agency's regulation by adding a requirement to provide records in any requested form or format if the record is readily reproducible by the agency in the requested form or format. FDA offices responsible for responding to FOIA requests shall make reasonable efforts to maintain their records in forms or formats that are readily reproducible for FOIA purposes. Because of the wide range of possible forms and formats, a specific office responding to a FOIA request may not have means to respond to requests in all requested forms and formats. In its proposal, the agency noted that it is striving toward a common records filing structure that will enhance the agency's ability to respond to requests for records in a particular form or format.

The comment asked whether FDA has requested input from its constituents with regard to a common record filing structure, and, if not, recommended that FDA do so.

FDA has not requested input from its constituents on this matter, but will take this comment into consideration as the agency continues to develop a common records filing structure. However, until such a structure is in place, FDA will respond to requests for records in specified forms or formats based on its existing technological and resource capabilities.

B. Section 20.34—Search for Records

The proposal stated that in responding to a request for records, the agency shall make reasonable efforts to search for records kept in their electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

The comment recommended that the agency provide an example of the kind of requests FDA believes would significantly interfere with the operation of the agency's automated information systems.

It is not readily possible for FDA to provide examples of situations that would significantly interfere with the operation of the agency's automated information systems. Because FDA has a decentralized system for processing FOIA requests, what constitutes significant interference may depend on the technical capabilities and resources of the particular office processing a request. Thus, the agency will be making these decisions on a case by case basis.

C. Section 20.40—Filing a Request for Records

As stated in the proposal, FDA will accept FOI requests via facsimile as well as via mail.

The comment requested that FDA also add e-mail as an acceptable means of filing a FOIA request in light of the common use of e-mail in today's business world. The agency is exploring the possibility of accepting electronic FOI requests, and at some future time may amend its regulations to permit the filing of electronic requests.

D. Section 20.44—Expedited Processing

The proposal implements section 8 of EFOIA, which requires agencies to provide for expedited processing of FOIA requests in cases where the person requesting the records demonstrates a ''compelling need'' and in other cases as determined by the agency.

The comment expressed concern that the scope of individuals or entities that can demonstrate ''compelling need'' is too narrow. In particular, the comment stated that the rule should be restructured so that pharmaceutical and other healthcare companies would also be in a position to obtain expedited processing when there is an urgency to inform the public about FDA regulatory activity, such as product recalls.

The definition of ''compelling need'' is set forth in the EFOIA statute (5 U.S.C. 552(a)(6)(E)) itself and cannot be changed by agency rulemaking. However, because EFOIA also permits agencies to grant expedited processing in other cases as determined by the agency, in those instances where the requester does not meet the statutory definition of ''compelling need'' but demonstrates a need for expedited processing, the agency has the discretion to grant such requests.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (i) 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.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule provides for greater flexibility in making requests, increased access to public information, and in certain cases, a faster agency response, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million, adjusted annually for inflation. As noted above, we find that this final rule would not have an effect of this magnitude on the economy.

VI. Paperwork Reduction Act of 1995

The 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.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 720

Confidential business information, Cosmetics.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Freedom of Information Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 14, 20, 314, and 720 are amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112, 42 U.S.C. 201, 262, 263b, 264.

§ 10.20 [Amended]

■ 2. Section 10.20 *Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure* is amended in paragraph (c)(6) by removing the last sentence and in paragraph (j)(2)(ii) by removing ''§ 20.46'' and by adding in its place ''§ 20.48''.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 3. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.61 [Amended]

■ 4. Section 14.61 *Transcripts of advisory committee meetings* is amended in paragraph (d) by removing ''§ 20.42'' and by adding in its place ''§ 20.45'' and by removing ''§ 20.51'' and by adding in its place ''§ 20.53''.

PART 20—PUBLIC INFORMATION

■ 5. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 6. Section 20.20 is amended by adding paragraph (e) to read as follows:

§ 20.20 Policy on disclosure of Food and Drug Administration records.

* * * * *

(e) ''Record'' and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained by the agency in any format, including an electronic format.

■ 7. Section 20.22 is amended by redesignating the existing paragraph as paragraph (a) and by adding paragraph (b) to read as follows:

§ 20.22 Partial disclosure of records.

(a) * * *

(b)(1) Whenever information is deleted from a record that contains both disclosable and nondisclosable information, the amount of information deleted shall be indicated on the portion of the record that is made available, unless including that indication would harm an interest protected by an exemption under the Freedom of Information Act.

(2) When technically feasible, the amount of information deleted shall be indicated at the place in the record where the deletion is made.

■ 8. Section 20.26 is amended by adding paragraph (a)(4) and by revising paragraph (b) to read as follows:

§ 20.26 Indexes of certain records.

(a) * * *

(4) Records that have been released to any person in response to a Freedom of Information request and that the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available through the Internet at http://www.fda.gov. A printed copy of each index is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room in rm. 12A–30 at the same address.

§ 20.27 [Amended]

■ 9. Section 20.27 *Submission of records marked as confidential* is amended by removing the phrase ''to review them pursuant to the procedures established in § 20.44,''

§ 20.28 [Amended]

■ 10. *Section 20.28 Food and Drug Administration determinations of confidentiality* is amended by removing the phrase ''or by a written determination pursuant to the procedure established in § 20.44''.

§ 20.29 [Amended]

■ 11. Section 20.29 *Prohibition on withdrawal of records from Food and Drug Administration files* is amended by removing the phrase ''Except pursuant to the procedures established in § 20.44 for presubmission review of records, no'' from the first sentence and by adding in its place the word ''No''.

■ 12. Subpart B is amended by adding §§ 20.33 and 20.34 to read as follows:

§ 20.33 Form or format of response.

(a) The Food and Drug Administration shall make reasonable efforts to provide a record in any requested form or format if the record is readily reproducible by the agency in that form or format.

(b) If the agency determines that a record is not readily reproducible in the requested form or format, the agency may notify the requester of alternative forms and formats that are available. If the requester does not express a preference for an alternative in response to such notification, the agency may provide its response in the form and format of the agency's choice.

§ 20.34 Search for records.

(a) In responding to a request for records, the Food and Drug Administration shall make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

(b) The term ''search'' means to review, manually or by automated means, agency records for the purpose of locating those records that are responsive to the request.

■ 13. Section 20.40 is amended by revising paragraph (a) to read as follows:

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, or by faxing it to 301–443–1726. All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

* * * * *

■ 14. Section 20.41 is amended by revising the introductory text of paragraph (b) and paragraph (b)(3), in paragraph (b)(2) by removing ''§ 20.45'' and by adding in its place ''§ 20.47'', and by adding paragraph (c) to read as follows:

§ 20.41 Time limitations.

* * * * *

(b) Within 20 working days (excluding Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial.

* * * * *

(3) (i) In unusual circumstances, the agency may extend the time for sending the letter for an additional period.

(A) The agency may provide for an extension of up to 10 working days by providing written notice to the requester setting out the reasons for the extension and the date by which a determination is expected to be sent.

(B) The agency may provide for an extension of more than 10 working days by providing written notice to the requester setting out the reasons for the extension. The notice also will give the requester an opportunity to limit the

scope of the request so that it may be processed in a shorter time and/or an opportunity to agree on a timeframe longer than the 10 extra working days for processing the request.

(ii) Unusual circumstances may exist under any of the following conditions:

(A) There is a need to search for and collect the requested records from field facilities or other components that are separate from the agency component responsible for processing the request;

(B) There is a need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(C) There is need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request, or among two or more components of the Food and Drug Administration having substantial subject-matter interest in the determination.

* * * * *

(c) The Food and Drug Administration shall provide a determination of whether to provide expedited processing within 10 calendar days of receipt by the Freedom of Information Staff of the request and the required documentation of compelling need in accordance with § 20.44(b).

■ 15. Sections 20.45 through 20.53 are redesignated as §§ 20.47 through 20.55, §§ 20.42 and 20.43 are redesignated as §§ 20.45 and 20.46, new §§ 20.42 and 20.43 are added, and § 20.44 is revised, to read as follows:

§ 20.42 Aggregation of certain requests.

The Food and Drug Administration may aggregate certain requests by the same requester, or by a group of requesters acting in concert, if the requests involve clearly related matters and the agency reasonably believes that such requests actually constitute a single request which would otherwise satisfy the unusual circumstances specified in § 20.41(b)(3)(ii)(B). FDA may extend the time for processing aggregated requests in accordance with the unusual circumstances provisions of § 20.41.

§ 20.43 Multitrack processing.

(a) Each Food and Drug Administration component is responsible for determining whether to use a multitrack system to process requests for records maintained by that component. A multitrack system provides two or more tracks for processing requests, based on the amount of work and/or time required for a request to be processed. The availability of multitrack processing does not affect expedited processing in accordance with § 20.44.

(b) If multitrack processing is not adopted by a particular agency component, that component will process all requests in a single track, ordinarily on a first-in, first-out basis.

(c) If a multitrack processing system is established by a particular agency component, that component may determine how many tracks to establish and the specific criteria for assigning requests to each track. Multiple tracks may be established for requests based on the amount of work and/or time required for a request to be processed.

(d) Requests assigned to a given track will ordinarily be processed on a first-in, first-out basis within that track.

(e) If a request does not qualify for the fastest processing track, the requester may be provided an opportunity to limit the scope of the request in order to qualify for faster processing.

§ 20.44 Expedited processing.

(a) The Food and Drug Administration will provide expedited processing of a request for records when the requester demonstrates a compelling need, or in other cases as determined by the agency. A compelling need exists when:

(1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.

(b) A request for expedited processing made under paragraph (a)(1) of this section must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other authorized representative of the individual, and must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the individual.

(c) A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:

(1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;

(2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and

(3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

(d) All requests for expedited processing shall be filed in writing as provided by § 20.40. Each such request shall include information that demonstrates a reasonable basis for concluding that a compelling need exists within the meaning of paragraph (a) of this section and a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief. Any statements made in support of a request for expedited processing are subject to the False Reports to the Government Act (18 U.S.C. 1001).

(e) The Assistant Commissioner for Public Affairs (or delegatee) will determine whether to grant a request for expedited processing within 10 days of receipt by the Freedom of Information Staff of all information required to make a decision.

(f) If the agency grants a request for expedited processing, the agency shall process the request as soon as practicable.

(g) If the agency denies a request for expedited processing, the agency shall process the request with other nonexpedited requests.

(h) If the agency denies a request for expedited processing, the requester may appeal the agency's decision by writing to the official identified in the denial letter.

■ 16. Newly redesignated § 20.45 is amended in paragraph (a) introductory text by removing ''§ 20.43'' and by adding in its place ''§ 20.46'', by revising the introductory text of paragraph (c), by removing the third sentence in paragraph (c)(1), and by revising paragraph (c)(6) to read as follows:

§ 20.45 Fees to be charged.

* * * * *

(c) *Fee schedule.* The Food and Drug Administration charges the following fees in accordance with the regulations of the Department of Health and Human Services at 45 CFR part 5.

* * * * *

(6) *Sending records by express mail or other special methods.* This service is not required by the Freedom of Information Act. If the Food and Drug Administration agrees to provide this service, the requester will be required to directly pay, or be directly charged by, the courier. The agency will not agree to any special delivery method that does

not permit the requester to directly pay or be directly charged for the service.

* * * * *

■ 17. Newly redesignated § 20.46 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 20.46 Waiver or reduction of fees.

(a) *Standard.* The Assistant Commissioner for Public Affairs (or delegatee) will waive or reduce the fees that would otherwise be charged if disclosure of the information meets both of the following tests:

* * * * *

§ 20.48 [Amended]

■ 18. Newly redesignated § 20.48 *Judicial review of proposed disclosure* is amended by removing ''§ 20.45'' and by adding in its place ''§ 20.47''.

■ 19. Newly redesignated § 20.49 is amended by revising paragraphs (a) and (c) to read as follows:

§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

* * * * *

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

* * * * *

§ 20.53 [Amended]

■ 20. Newly redesignated § 20.53 is amended by removing ''§ 20.42'' and by adding in its place ''§ 20.45''.

§ 20.81 [Amended]

■ 21. Section 20.81 *Data and information previously disclosed to the public* is amended by removing paragraph (b) and by redesignating paragraph (c) as new paragraph (b).

§ 20.83 [Amended]

■ 22. Section 20.83*Disclosure required by court order* is amended in paragraph (a) by removing ''either'' and by removing the phrase ''or by a written determination pursuant to the procedure established in § 20.44''.

■ 23. Section 20.107 is amended by revising paragraph (a) to read as follows:

§ 20.107 Food and Drug Administration manuals.

(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. An index of all such manuals is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room, located in rm. 12A–30 at the same address. The index and all manuals created by the agency on or after November 1, 1996, will be made available through the Internet at http://www.fda.gov.

* * * * *

§ 20.111 [Amended]

■ 24. Section 20.111 *Data and information submitted voluntarily to the Food and Drug Administration* is amended in paragraph (b) by removing the phrase ''or by a written determination pursuant to the procedure established in § 20.44'' and in paragraph (c)(4) by removing the last sentence.

■ 25. Section 20.120 is added to subpart F to read as follows:

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Food and Drug Administration operates two public reading rooms. The Freedom of Information Staff's Public Reading Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, the phone number is 301–827–6500. The Dockets Management Branch's Public Reading Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20857; the phone number is 301–827–6860. Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

(b) The following records are available at the Freedom of Information Staff's Public Reading Room:

(1) A guide for making requests for records or information from the Food and Drug Administration;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Food and Drug Administration records which have been released to any person in response to a Freedom of Information request and which the agency has determined have become or are likely to become the subject of subsequent requests for substantially the same records;

(4) Indexes of records maintained in the Freedom of Information Staff's Public Reading Room; and

(5) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(c) The following records are available in the Dockets Management Branch's Public Reading Room:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by the agency that are still in force and not published in the **Federal Register**;

(3) Indexes of records maintained in the Dockets Management Branch's Public Reading Room; and

(4) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(d) The agency will make reading room records created by the Food and Drug Administration on or after November 1, 1996, available electronically through the Internet at the agency's World Wide Web site which can be found at http://www.fda.gov. At the agency's discretion, the Food and Drug Administration may also make available through the Internet such additional records and information it believes will be useful to the public.

PART 314—APPLICATION FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 26. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.65 [Amended]

■ 27. Section 314.65*Withdrawal by the applicant of an unapproved application* is amended by removing ''§ 20.42'' and by adding in its place ''§ 20.45''.

§ 314.72 [Amended]

■ 28. Section 314.72 *Change in ownership of an application*is amended in paragraph (a)(2)(iii) by removing ''§ 20.42'' and by adding in its place ''§ 20.45''.

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

■ 29. The authority citation for 21 CFR part 720 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 361, 362, 371, 374.

§ 720.8 [Amended]

■ 30. Section 720.8 *Confidentiality of statements* is amended by removing from the second sentence of paragraph (a) the phrase ''and in § 20.44 of this chapter''.

Dated: May 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11647 Filed 5–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Diego 03–010]

RIN 1625–AA00 [Formerly RIN 2115–AA97]

Security Zones; San Diego Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is expanding the geographical boundaries of the permanent security zones at Naval Base San Diego; Naval Submarine Base, San Diego; and Naval Base Coronado, California at the request of the U.S. Navy. Modification and expansion of these security zones is needed to ensure the physical protection of naval vessels moored within each zone by accommodating the Navy's placement of anti-small boat barrier booms within the zones. Entry into these zones is prohibited unless authorized by the Captain of the Port (COTP) San Diego; Commander, Naval Base San Diego; Commander, Naval Base Point Loma; Commander, Naval Base Coronado; or Commander, Navy Region Southwest.

DATES: The suspension of 33 CFR 165.1101, 165.1103, and 165.1104 (effective from 11:59 p.m. on February 11, 2003 to 11:59 p.m. on May 12, 2003, published in the **Federal Register** at 68 FR 7073–7080, on February 12, 2003) is lifted effective 11:59 p.m. on April 14, 2003. This rule is effective on April 15, 2003.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [COTP San Diego 03–010] and are available for inspection or copying at Coast Guard Marine Safety Office San Diego, 2716 North Harbor Drive, San Diego, California, 92101. Marine Safety Office San Diego, Port Operations Department between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Joseph Brown, Port Safety and Security, at (619) 683–6495.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 11, 2003, we published a notice of proposed rulemaking (NPRM) entitled [Security Zones; San Diego Bay, CA] in the **Federal Register** (68 FR 6844). We received 0 letters commenting on the proposed rule. No public hearing was requested, and none was held.

Under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Maritime Administration (MARAD) recently issued MARAD Advisory 03–03 (182100Z MAR 03) informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attacks to the maritime community in the United States. Further, national security and intelligence officials warn that future terrorist attacks against United States interests are likely. The measures contemplated by the rule are intended to prevent waterborne acts of sabotage or terrorism, which terrorists have demonstrated a capability to carry out. Any delay in making this regulation effective would be contrary to the public interest because immediate action is necessary to protect U.S. naval interests against the possible loss of life, injury, or damage to property.

Background and Purpose

On September 16th and 17th, 2002, the Coast Guard published three temporary final rules suspending 33 CFR 165.1101, 33 CFR 165.1103, and 33 CFR 165.1104 and implementing temporary security zones at Naval Base San Diego, Naval Base Coronado, and Naval Submarine Base San Diego. See 67 FR 58524, 67 FR 58526, and 67 FR 58333. Modified versions of these zones have been in place since 1998 and the Coast Guard has not received any comments during that time and no negative incidents have been reported.

The U.S. Navy requested that the Coast Guard implement these security zones in coordination with their installation of anti-small boat barrier booms at the three locations. If you would like to obtain information about the U.S. Navy's action, contact the Assistant Chief of Port Operations, Navy Region Southwest at 619–556–2400.

The Coast Guard is modifying the security zones to allow the U.S. Navy to put anti-small boat barrier booms at Naval Base San Diego (33 CFR 165.1101); Naval Submarine Base, San Diego (33 CFR 165.1103); and Naval Base Coronado (33 CFR 165.1104). The modification and expansion of these security zones is needed to ensure the physical protection of naval vessels moored in the area by providing adequate standoff distance. The Coast Guard's action supports the Navy's action and is limited to the expansion of the existing zones.

The modification and expansion of these security zones will also prevent recreational and commercial craft from interfering with military operations involving all naval vessels home-ported at Naval Base Coronado, Naval Submarine Base San Diego, and Naval Base San Diego, and it will protect transiting recreational and commercial vessels, and their respective crews, from the navigational hazards posed by such military operations. It will also safeguard vessels and waterside facilities from destruction, loss, or injury from sabotage or other subversive acts, accidents, or other causes of a similar nature. Entry into, transit through, or anchoring within this security zone is prohibited unless authorized by the Captain of the Port San Diego; Commander, Naval Base San Diego; Commander, Naval Base Point Loma; Commander, Naval Base Coronado; or Commander, Navy Region Southwest.

Discussion of Rule

Specifically, the Coast Guard is expanding the security zone boundaries at the request of the U.S. Navy so that the U.S. Navy can install anti-small boat barrier booms.

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress amended section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950 (50 U.S.C. 191 *et seq.*) and implementing regulations promulgated by the President in Subparts 6.01 and 6.04 of Part 6 of Title 33 of the Code of Federal Regulations.

Vessels or persons violating this section will be subject to the penalties