(k) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198, telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0014, dated January 25, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0014, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on August 19, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–19746 Filed 9–12–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20 and 720

[Docket No. FDA–2018–N–1622]

RIN 0910–AH69

Public Information

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule amending its public information regulations. The final rule revises the current regulations to incorporate changes made to the Freedom of Information Act (FOIA) by the Openness Promotes Effectiveness in our National Government Act of 2007 (OPEN Government Act) and the FOIA Improvement Act of 2016 (FOIA Improvement Act). Additionally, the final rule updates the current regulations to reflect changes to the organizational structure of FDA, to make the FOIA process easier for the public to navigate, and to make provisions clearer.

DATES: This rule is effective October 13, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sarah B. Kotler, Office of the Commissioner, Office of the Executive Secretariat, Food and Drug Administration, 5630 Fishers Lane, Rm. 1050, Rockville, MD 20857, 301–796–3900, *FDAFOIA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend FDA's public information regulations. The regulations are being amended to incorporate changes made to the FOIA by the OPEN Government Act and the FOIA Improvement Act. Additionally, the final rule updates the regulations to reflect changes to the organizational structure of FDA, makes the FOIA process easier for the public to navigate, and makes certain provisions clearer. Taken together, these changes enhance transparency for the public about FDA activities.

B. Summary of the Major Provisions of the Final Rule

The amendments to FDA's public information regulations bring the Agency's regulations in line with statutory amendments to the FOIA, update cross references to other statutes and parts of the Agency's regulations, and clarify certain provisions with minor editorial updates.

C. Legal Authority

These amendments to FDA's public information regulations are based on our authority under the FOIA and the Federal Food, Drug, and Cosmetic Act (FD&C Act). These amendments allow FDA to more efficiently use its resources to provide information to the public.

D. Costs and Benefits

Although FDA is currently implementing the requirements of the OPEN Government Act and the FOIA Improvement Act in FOIA processing as standard practice, the requirements are not currently reflected in FDA regulations. The revisions made by this final rule are intended to incorporate all current FOIA requirements into the existing regulations. Because the Agency has already adopted many of these requirements, we anticipate no additional costs or benefits from this final rule.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/ Acronym	What it means
FOIA	Freedom of Information Act.
FOIA Improvement Act.	FOIA Improvement Act of 2016.
OGIS	Office of Government Information Services.
OPEN Government Act.	Openness Promotes Effectiveness in our National Government Act of 2007.

III. Background

The FOIA (5 U.S.C. 552) is a law that gives the public the right to access information from the Federal Government. There is a presumption that government records must be released under the FOIA unless they are subject to one of nine FOIA exemptions. FDA's regulations for the implementation of the FOIA are in part 20 of title 21 of the Code of Federal

Regulations (CFR). The FOIA Improvement Act (Pub. L. 114–185) specifically requires agencies to review their FOIA regulations and update their regulations for the disclosure of records in accordance with its amendments.

IV. Legal Authority

These amendments to FDA's public information regulations are based on FDA's authority under the FOIA and section 701(a) of the FD&C Act (21 U.S.C. 371(a)). These revised regulations allow FDA to more efficiently use its resources to provide information to the public.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

FDA received comments on the proposed rule (83 FR 46437, September 13, 2018) (hereinafter referred to as the proposed rule) from industry, various entities, academia, and individuals. A summary of the comments submitted to the docket and the Agency's responses follow. We have numbered each comment to help distinguish among different comments. We have grouped similar comments together under the same number and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of the responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance, or the order in which comments were received.

B. Description of Comments Regarding 21 CFR Parts 20 and 720

(Comment 1) One comment supported the proposed rule.

(Response 1) We acknowledge and appreciate the supportive comment.

(Comment 2) One comment expressed concern with FDA's characterization of the foreseeable harm standard with respect to discretionary disclosures and requested that FDA clarify that ''such disclosures are mandatory'' under 5 U.S.C. 552(8)(A).

(Response 2) Although the commenter identified 5 U.S.C. 552(8)(A), based on the content of the comment, we presume the commenter meant to identify 5 U.S.C. 552(a)(8)(A). FDA has revised the provision for clarity and to conform more closely to the text of 5 U.S.C. 552(a)(8)(A).

(Comment 3) One comment ''applaud[ed] the proposed revisions to § 20.20(c) [21 CFR 20.20(c)], which require the FDA to identify records of general interest to the public for posting on its website.'' This comment also requests that FDA ''take the opportunity to re-examine and implement the recommendations contained in the 'Blueprint for Transparency at the U.S. Food and Drug Administration', which provides a list of proactive changes that FDA can make to increase transparency under existing law.''

(Response 3) FDA appreciates this comment. In an effort to make the FOIA process easier for the public to navigate, FDA proposed this rule to provide clarity and consistency regarding the public's access to records. FDA believes the changes will promote transparency by reducing the amount of information withheld when the Agency has discretion to determine what will be withheld under the FOIA exemptions and will make release of information more efficient through the use of information technology.

(Comment 4) One comment requested clarification of the codified language of § 20.26(a)(4) [21 CFR 20.26(a)(4)]. The comment expressed concern that the language used to reflect the new statutory requirement for FDA to make available for public inspection all records ''that have been released to any person'' pursuant to a FOIA request and ''that have been requested three or more times'' may be misconstrued. The comment asserted that, as drafted, the proposed revision does not make clear that records required to be made available for public inspection must have been previously released to a person pursuant to a FOIA request. Rather, the wording of the proposal ''could be interpreted to authorize the release of any records that have been requested three or more times, regardless of whether these records have previously been released under the FOIA or are protected from disclosure pursuant to an applicable FOIA exemption.''

(Response 4) After considering this comment, FDA has amended the provision to make clear that § 20.26(a)(4) applies only to records that have been released to any person under the FOIA. Specifically, the provision now refers to records that have been released to any person in response to a FOIA request, and that (1) the Agency has determined have become, or are likely to become, the subject of subsequent FOIA requests for substantially the same records, or (2) have been requested three or more times under the Freedom of Information Act.

(Comment 5) One comment supported revisions to § 20.26(a)(4) to make records that have been released to any person pursuant to a FOIA request available on the electronic reading room site, after three FOIA requests have been made for the same records. The comment requested that FDA ''promptly comply with the requirements for posting documents on its website after three FOIA requests are received.''

(Response 5) Where a record has been released to any person in response to a FOIA request and has been requested three or more times under the FOIA, FDA intends to publicly post the record.

(Comment 6) One comment requested that FDA ''provide more information about the processing of FOIA requests, including applicable timelines, to enhance predictability and transparency.'' The comment asserted that ''there currently are no clear agency timelines associated with the processing of FOIA requests and no clear mechanism for a requester to learn the status of its FOIA request.'' Specifically, the request asked for ''more information about how it processes FOIA requests and the estimated timelines associated with each step (such as through a process flow diagram)'' and the allowance of ''sufficient time and flexibility to account for the redaction of protected information.''

(Response 6) FDA appreciates suggestions to improve the FOIA process and intends to take this comment into consideration when developing and revising processes. FDA believes including these as requirements in part 20 is not needed and could be unduly inflexible.

(Comment 7) One comment requested that FDA modify § 20.41(a) [21 CFR 20.41(a)] to include language ''clearly stating that any time limitation calculations begin at the time of receipt of a request, not the time that the request is logged.'' The comment asserted that ''[§] 20.41 of the FDA's current FOIA regulations—which is not addressed by the Proposed Rule—calculates various time limitations under the Act starting at 'the time at which a request for records is logged in by the Division of Freedom of Information pursuant to § 20.40(c) [21 CFR 20.40(c)].' ''

(Response 7) FDA is required by the FOIA to ''determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of [a] request whether to comply with such request'' (5 U.S.C 552(a)(6)(A)(i)). The FOIA states that the 20-day period commences ''on the date on which the request is first received by the appropriate component of the agency, but in any event not later than ten days after the request is first received by any component of the agency that is designated in the agency's regulations

. . . to receive [FOIA] requests'' (5 U.S.C. 552(a)(6)(A)(ii)). FDA logs requests in accordance with its statutory obligations pursuant to § 20.40(c), which establishes the date used to calculate time limitations under § 20.41(a).

(Comment 8) One comment requested that FDA modify § 20.44(e) [21 CFR 20.44(e)] to reflect the same language in 5 U.S.C. 552 (a)(6)(E)(ii)(I), which provides that ''a determination of whether to provide expedited processing shall be made, and notice of the determination shall be provided to the person making the request, within 10 days after the date of the request.'' The language of the proposed rule states that FDA ''will determine whether to grant a request for expedited processing within 10 days of receipt by the Division of Freedom of Information of all information required to make a decision.'' (83 FR 46437 at 46441) The comment asserted that because the proposed rule does not include a definition of what is considered to be ''all information required to make a decision'' in a request for expedited processing, the language should be revised to mirror 5 U.S.C. 552(a)(6)(E)(ii)(I).

(Response 8) FDA has provided for a decision within the 10-day period when it is possible based on the information submitted to the Agency. Agencies are required to provide for expedited processing of FOIA requests in cases where requests for expedited processing show a compelling need. However, the FOIA 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 based on all information required to make a decision. We do not provide a definition of ''all information required to make a decision'' as the circumstances of each situation are unique and a decision is made on a case-by-case-basis. In some situations, FDA may ask the requester for additional information rather than deny the request for expedited process on the basis that it did not meet the required showing.

(Comment 9) One comment asked that FDA ''update its FOIA regulations to expressly require consultation and/or notification when any such information may possibly be viewed as trade secret or confidential commercial information. FDA, as part of such an initiative, should also adequately ensure that submitters of sensitive information throughout the supply chain are actually notified.'' The comment asserted that newly promulgated regulations under the FDA Food Safety Modernization Act (Pub. L. 111–353) ''require the submission of an unprecedented amount of information held by firms throughout the food supply chain, meaning such records will potentially be subject to public disclosure upon submission of an appropriate FOIA request or through other voluntary disclosure by FDA.''

Currently, § 20.47 provides that in situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, FDA will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure. Section 20.61 [21 CFR 20.61] further provides that ''when the agency has substantial reason to believe that information in [requested] records could reasonably be considered exempt under [E]xemption 4'' the Agency must ''make reasonable efforts to notify the submitter about these facts.'' The comment alleged that although ''these regulations provide for submitter consultation and notification in certain circumstances, in practice, FDA frequently response (sic) to requests for this information without first engaging with submitters.'' Importantly, even though ''FOIA itself does not require agencies to notify submitters that confidential business information may be subject to disclosure, agencies must provide for submitter notification in their regulations or through other procedures under Executive Order 12600.''

(Response 9) FDA believes no change to the provision is needed because where confidentiality of data or information is uncertain, FDA will consult with the person who submitted the information ''or who would be affected by the disclosure.''

Agency regulations currently satisfy the requirements of Executive Order 12600, and we do not believe a change is otherwise warranted.

(Comment 10) One comment requested that FDA modify § 20.88(d) [21 CFR 20.88(d)] to clarify that FDA cannot ask State or local government entities to enter into contracts that would violate State law.

(Response 10) The final rule adopts the language proposed in § 20.88(d) and does not require State or local government entities to enter into contracts or other agreements that conflict with the requirements of their State public record laws. Under § 20.88(d)(1)(i), the State or local government agency must first provide a written statement establishing its authority to protect confidential commercial information from public disclosure. In providing a written statement to this effect, the State or local government agency should determine whether it has the necessary authority under State law to protect confidential commercial information. If so, the written agreement to protect such information should not conflict with State law. Furthermore, a written agreement would not override a State's obligation to comply with applicable law. If the State or local agency determines that it does not have such authority, it will be unable to provide a written statement and FDA, in turn, will be unable to authorize the disclosure of confidential commercial information to the State or local government agency.

C. Description of Comments Outside the Scope of This Rulemaking

(Comment 11) One comment suggested that FDA request funding to hire sufficient additional staff to expedite response capability pursuant to § 20.41.

(Response 11) The suggestion is outside the scope of this rulemaking.

(Comment 12) One comment suggested that publicly released FOIA logs should include metadata such as type of file/document released, size of the file/document released, and number of rows per file if data files are released.

(Response 12) The suggestion is outside the scope of this rulemaking.

(Comment 13) One comment suggested that exemptions used by the Federal Government should be restricted as a matter of public policy, especially when it comes to FDA.

(Response 13) The suggestion is outside the scope of this rulemaking.

VI. Description of the Final Rule

We are amending provisions of 21 CFR part 20 regarding the Agency's public information regulations. Once effective, the amendments contained in this rule will apply to all FOIA requests currently pending with, or received in the future by, FDA.

- The amendments to § 20.20 require FDA to withhold information under the FOIA only if the Agency reasonably foresees that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law. The rule further amends this provision to require FDA to establish procedures for identifying records of general interest or use to the public that are appropriate for public disclosure, and for posting such records in a publicly accessible

electronic format. These changes promote transparency by reducing the amount of information that will be withheld when the Agency has discretion to determine what will be withheld under the FOIA exemptions, and will make release of information more efficient through the use of information technology. These amendments are required by the FOIA Improvement Act and are currently part of FDA's FOIA policy and procedures.

- The amendment to 21 CFR 20.22 requires FDA to indicate the exemption(s) under which information has been deleted at the site of the deletion. This change will inform requesters of the legal bases under which information has been withheld from Agency records, which promotes transparency. This change is required by the OPEN Government Act (Pub. L. 110–175) and was adopted by the Agency for FOIA processing as of the effective date of the OPEN Government Act.
- The amendment to § 20.26 requires FDA to make available for public inspection in an electronic format records that have been requested three or more times under the FOIA and have been released to a requester under the FOIA. This change codifies the long-standing Department of Justice policy of Federal agencies posting records that have been requested three or more times. The purpose of this change is to proactively release records to the public without the need for submission of additional FOIA requests. This change is required by the FOIA Improvement Act.
- The amendment to 21 CFR 20.33 requires FDA to include in FOIA response letters the contact information for the Office of Government Information Services (OGIS) and the FOIA Public Liaison. This change provides requesters with additional avenues for resolving FOIA-related disputes beyond the appeals process. This provision is required by the FOIA Improvement Act.
- The amendment to § 20.40 [21 CFR 20.40] updates the provision to include reference to the Agency's online FOIA submission portal, which has been operational since June 2012.
- The amendment to § 20.41 requires that when FDA extends the time limit to respond to requests by up to10 additional working days, FDA must notify the requester in writing of the right to contact the FOIA Public Liaison and to seek dispute resolution services from the OGIS. This change provides requesters with additional avenues for resolving FOIA-related disputes beyond the appeals process. We further amended the provision to provide that if a court determines that exceptional circumstances exist, the Agency's failure to comply with a time limit shall be excused for the length of time provided by the court order. These changes are required by the FOIA Improvement Act. The revised provision further clarifies that the Agency may toll the response period once while it is awaiting a response from the requester regarding clarification that it has reasonably requested from the requester and more than once (if necessary) while the Agency is awaiting a response from the requester regarding fee assessment. This revision is required by the OPEN Government Act. Finally the revised provision contains minor updates regarding the appeal of an adverse determination.
- The amendment to § 20.44 updates the title of the Agency official making determinations regarding requests for expedited processing.
- The amendments to 21 CFR 20.45 modify the fee schedule to prohibit the Agency from assessing fees if the Agency fails to comply with time limits to respond and there are no unusual or exceptional circumstances that apply to the processing of the request. If unusual circumstances apply, these amendments establish a process by which the Agency can work with the requester to effectively limit the scope of the request. These changes provide an incentive to the Agency to process requests as efficiently as possible and provide fee relief to requesters who do not receive FOIA responses in a timely manner. These provisions are required by the OPEN Government Act. Further amendments to this provision clarify how fees are calculated.
- The rule amends § 20.49(c) [21 CFR 20.49(c)] to require full and partial denial letters to include contact information for the FOIA Public Liaison and OGIS, and to establish a 90 calendar day timeframe for transmittal of an appeal. We also made technical revisions to § 20.49(a) to update the position title of the person who signs a denial of a request for records and to § 20.49(c) regarding information provided about appeals. These changes provide requesters with additional avenues for resolving FOIA-related disputes beyond the appeals process and provide requesters with additional time to decide whether to pursue an appeal. Some of these amendments are required by the FOIA Improvement Act.
- The rule amends § 20.61(e)(2) to allow 10 days from the date of the notice for submitters of trade secrets or confidential commercial information to object to disclosure. The revised provision further states that the Division of Freedom of Information may extend this period as appropriate and necessary. This change brings the Agency in line with HHS regulations in 45 CFR 5.42(a)(2).
- The rule amends 21 CFR 20.62 to prohibit the application of the deliberative process privilege under Exemption 5 of the FOIA to records created 25 years or more before the date on which the records were requested. This change increases transparency by requiring the Agency to release information that could otherwise fall within the deliberative process privilege. This amendment is required by the FOIA Improvement Act.
- The amendment to 21 CFR 20.82 clarifies the discretionary disclosure standard outlined in that provision that guides the Agency's determination to disclose requested information, taking into account whether disclosure of information would reasonably foreseeably harm an interest protected by an exemption or is prohibited by law as required in administering § 20.20.
- The amendment to 21 CFR 20.85 updates the statutory references.
- The amendment to 21 CFR 20.86 clarifies that the list of proceedings subject to the provision is not exclusive.
- The amendments to § 20.88 clarify that the provisions also apply to local officials and remove references to position titles that no longer exist.
- The amendments to 21 CFR 20.89 remove references to position titles that no longer exist.
- The amendments to 21 CFR 20.100 update the regulatory cross-references.
- The amendment to 21 CFR 20.120 updates the contact information for the Agency's reading rooms.
- The amendment to 21 CFR 720.8 revises the request for confidentiality of the identity of a cosmetic ingredient provision for consistency with FDA's disclosure regulation at 21 CFR 20.29.

VII. Effective Date

This rule is effective October 13, 2022.

VIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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). This final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed revisions do not impose any burdens on FOIA requesters, including those that might be small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

We expect to incur only negligible costs associated with implementing this rule. These costs result from updating titles of Agency officials, providing some additional information to FOIA requesters, and compiling information for annual reports. These requirements would not require more resources from us because we would perform these actions as part of routine FDA practices for FOIA processing. The rule enhances public access to government information as required by the FOIA Improvement Act.

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) 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.

X. Paperwork Reduction Act of 1995

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

XI. Federalism

We have 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, we conclude 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.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

List of Subjects

21 CFR Part 20

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

21 CFR Part 720

Confidential business information, Cosmetics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20 and 720 are amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for 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, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. Revise § 20.20 to read as follows:

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

(a) The Food and Drug Administration (FDA) will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the Agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all FDA records shall be made available for public disclosure. FDA will withhold requested information only if:

(1) The Agency reasonably foresees that disclosure would harm an interest protected by an exemption described in this part; or

(2) Disclosure is prohibited by law.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless of whether any justification or need for such records have been shown.

(d) Under § 21.71 of this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be requested when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 21.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so retrieved or a person acting on his behalf; and

(3) The disclosure is one that is discretionary; *i.e.,* not required under this part.

(e) ''Record'' and any other term used in this part 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.

(f) FDA will establish procedures for identifying records of general interest or use to the public that are appropriate for public disclosure, and for posting and indexing such records in a publicly accessible electronic format.

■ 3. In § 20.22, add paragraph (b)(3) to read as follows:

§ 20.22 Partial disclosure of records.

* * * * *

(b) * * *

(3) The exemption(s) under which the information has been deleted shall be noted at the site of the deletion.

■ 4. In § 20.26, revise the section heading and paragraphs (a) introductory text, (a)(4), and (b) to read as follows:

§ 20.26 Electronic availability and indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, and, as required, copies of electronic records

shall be made available for the following Food and Drug Administration records:

* * * * *

(4) Records that have been released to any person in response to a Freedom of Information request, and that:

(i) The Agency has determined have become, or are likely to become, the subject of subsequent Freedom of Information requests for substantially the same records; or

(ii) Have been requested three or more times under the Freedom of Information Act.

(b) Each such record and index will be made available by accessing the Agency's website at *https://www.fda.gov.* A printed copy of each index is available by writing or visiting the Freedom of Information Staff's address on the Agency's website at *https://www.fda.gov.*

■ 5. In § 20.33, add paragraph (c) to read as follows:

§ 20.33 Form or format of response.

* * * * *

(c) Response letters shall contain contact information for the Freedom of Information Act (FOIA) Public Liaison and the Office of Government Information Services.

■ 6. In § 20.40, revise 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 at the address on the Agency's website at *https://www.fda.gov,* by faxing it to the fax number listed on the Agency's website at *https://www.fda.gov,* or by submission through the Agency's online FOIA submission portal at *https://www.fda.gov.* 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.

* * * * *

■ 7. In § 20.41:

■ a. Revise paragraph (b)(3)(i)(A);

■ b. Redesignate paragraph (b)(4) as paragraph (b)(5);

■ c. Add a new paragrpah (b)(4);

■ d. Revise newly redesignated paragraph (b)(5); and

■ e. Add paragraph (d).

The revisions and additions read as follows:

§ 20.41 Time limitations.

* * * * *

(b) * * *

(3)(i) * * *

(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. In the written notice, the Agency will inform the requester of the right to contact the Freedom of Information Act Public Liaison and to seek dispute resolution services from the Office of Government Information Services.

* * * * *

(4) The Agency may contact the requester for clarification about the request or regarding fee assessment. The Agency may toll the 20-day period as follows:

(i) One time while it is awaiting a response from the requester regarding clarification that it has reasonably requested from the requester; and

(ii) One or more times while the Agency is awaiting a response from the requester regarding fee assessment.

(5) If any record is denied, the letter shall state the right of the person requesting such record to appeal any adverse determination to the appropriate review official, in accordance with the provisions of 45 CFR 5.62.

* * * * *

(d) If a court determines that exceptional circumstances exist, as defined by the Freedom of Information Act, the Agency's failure to comply with a time limit shall be excused for the length of time provided by the court order.

■ 8. In § 20.44, revise paragraph (e) to read as follows:

§ 20.44 Expedited processing.

* * * * *

(e) The Director, Division of Freedom of Information, (or delegatee) will determine whether to grant a request for expedited processing within 10 days of receipt by the Division of Freedom of Information of all information required to make a decision.

* * * * *

■ 9. In § 20.45, revise paragraphs (a)(1) through (3), add paragraph (b)(7), and revise paragraphs (c)(1) and (2) to read as follows:

§ 20.45 Fees to be charged.

(a) * * *

(1) *Commercial use request.* If the request is for a commercial use, the Food and Drug Administration will charge for the costs of search, review, and duplication. The Agency shall not assess search fees if the Agency fails to comply with any time limit, as described in § 20.41, if no unusual or exceptional circumstances apply to the processing of the request. If unusual circumstances, as outlined in § 20.41, apply and more than 5,000 pages are responsive to the request, the Food and Drug Administration may charge search fees if timely written notice has been made to the requester and the Agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request.

(2) *Educational and scientific institutions and news media.* If the request is from an educational institution or a noncommercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and the request is not for a commercial use, the Food and Drug Administration will charge only for the duplication of documents. Also, the Food and Drug Administration will not charge the copying costs for the first 100 pages of duplication (or its cost equivalent of other media). The Agency shall not assess duplication fees if the Agency fails to comply with any time limit, as described in § 20.41, if no unusual or exceptional circumstances apply to the processing of the request. If unusual circumstances, as outlined in § 20.41, apply and more than 5,000 pages are responsive to the request, the Food and Drug Administration may charge duplication fees if timely written notice has been made to the requester and the Agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request.

(3) *Other requests.* If the request is not the kind described in paragraph (a)(1) or (a)(2) of this section, then the Food and Drug Administration will charge only for the search and the duplication. Also, the Food and Drug Administration will not charge for the first 2 hours of search time or for the copying costs of the first 100 pages of duplication (or the cost equivalent of other media). The Agency shall not assess search or duplication fees if the Agency fails to comply with any time limit, as described in § 20.41, if no unusual or exceptional circumstances apply to the processing of the request. If unusual circumstances, as outlined in § 20.41, apply and more than 5,000 pages are responsive to the request, the Food and Drug Administration may charge search or duplication fees if timely written notice has been made to the requester and the Agency has discussed with the requester

via written mail, electronic mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request.

(b) * * *

(7) Requesters may contact Agency Freedom of Information Act staff or the Freedom of Information Act Public Liaison to assist in reformulating a request to meet their needs at lower cost.

(c) * * *

(1) *Manual searching for or reviewing of records.* When the search or review is performed by employees at grade GS–1 through GS–8 (or equivalent), an hourly rate based on the salary of a GS–5, step 7, employee; when done by a GS–9 through GS–14 (or equivalent), an hourly rate based on the salary of a GS–12, step 4, employee; and when done by a GS–15 or above (or equivalent), an hourly rate based on the salary of a GS–15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate for the specified grade and step in the General Schedule Locality Pay Table for the Locality of Washington-Baltimore-Northern Virginia, DC–MD–VA–WV–PA, adding 16 percent of that rate to cover benefits, and rounding to the nearest whole dollar. When a search involves employees at more than one of these levels, the Food and Drug Administration will charge the rate appropriate for each.

(2) *Electronic searching.* Charges for the time spent by the operator to search the computer, database, or network, including development of any specialized programming required to perform the search, at the rate given in paragraph (c)(1) of this section plus the cost of any materials.

* * * * *

■ 10. In § 20.49:

■ a. Revise paragraphs (a) and (c); and

■ b. Remove paragraph (d).

The revisions 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 Director, Division of Freedom of Information (or delegatee).

* * * * *

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial, the appropriate review official and address to which the appeal should be sent, and that an appeal must be transmitted within 90 calendar days from the date of the adverse determination, in accordance with 45 CFR 5.61. 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. The letter will also include contact information for the Freedom of Information Act Public Liaison and the Office of Government Information Services.

■ 11. In § 20.61, revise paragraph (e)(2) to read as follows:

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

* * * * *

(e) * * *

(2) The submitter has 10 working days from the date of the notice to object to disclosure of any part of the records and to state all bases for its objections. The Division of Freedom of Information may extend this period as appropriate and necessary.

* * * * *

■ 12. Revise § 20.62 to read as follows:

§ 20.62 Inter- or intra-agency memoranda or letters.

Interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the Food and Drug Administration may be withheld from public disclosure except that factual information that is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure. The deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

■ 13. In § 20.82, revise paragraph (a) to read as follows:

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his or her discretion, disclose part or all of any Food and Drug Administration (FDA) record that is otherwise exempt from disclosure pursuant to subpart D of this part. As set forth in § 20.20(b), FDA will withhold requested information only if:

(1) The Agency reasonably foresees that disclosure would harm an interest protected by an exemption described in this part; or

(2) Disclosure is prohibited by law. FDA shall exercise its discretion to disclose such records whenever it determines that such disclosure is in the public interest, will promote the objectives of the Freedom of Information Act and the Agency, and is, for example, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the Agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

* * * * *

■ 14. Revise § 20.85 to read as follows:

§ 20.85 Disclosure to other Federal Government departments and agencies.

Any Food and Drug Administration (FDA) record otherwise exempt from public disclosure may be disclosed to other Federal Government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 21 U.S.C. 360ll(d), 21 U.S.C. 360nn(e), and 21 U.S.C. 387f(c) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of FDA.

■ 15. Revise § 20.86 to read as follows:

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration (FDA) administrative proceedings, such as those pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter, or court proceedings, where data or information are relevant. FDA will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

■ 16. In § 20.88, revise paragraphs (d)(1) introductory text, (d)(1)(i), (d)(1)(ii)(B) and (C), (d)(2), and (e)(1) and (3) to read as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(d)(1) The Commissioner of Food and Drugs (or delegatee) may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into Agency-prepared records, to State and local government officials as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The State or local government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) * * *

(B) Disclosure would be in the interest of public health by reason of the State or local government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State or local government being able to exercise its regulatory authority more expeditiously than the Food and Drug Administration; or

(C) The disclosure is to a State or local government scientist visiting the Food and Drug Administration on the Agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the Federal Food, Drug, and Cosmetic Act, the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting State or local government scientist to sign a written commitment to protect the confidentiality of the information, and the visiting State or local government scientist provides a written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the individual were subject to the conflict of interest rules applicable to the Food and Drug Administration advisory committee members under § 14.80(b)(1) of this chapter. Subject to all the foregoing conditions, a visiting State or local government scientist may have access to trade secret information, entitled to protection under section 301(j) of the Federal Food, Drug, and Cosmetic Act, in those cases where such disclosures would be a necessary part of the joint review or training.

(2) Except as provided under paragraph (d)(1)(ii)(C) of this section, the provisions of paragraph (d) of this section do not authorize the disclosure to State and local government officials of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the Federal Food, Drug, and Cosmetic Act, unless pursuant to an express written authorization provided by the submitter of the information.

* * * * *

(e)(1) The Commissioner of Food and Drugs or (delegatee), may authorize the disclosure to, or receipt from, an official of a State or local government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other Government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State and/or Federal-local uniformity, cooperative regulatory activities, or implementation of Federal-State and/or Federal-local agreements, provided that:

(i) The State or local government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Commissioner (or delegatee) makes the determination that the exchange is reasonably necessary to improve Federal-State and/or Federal-local uniformity, cooperative regulatory activities, or implementation of Federal-State and/or Federal-local agreements.

* * * * *

(3) For purposes of paragraph (e) of this section, the term *official of a State or local government agency* includes, but is not limited to, an agent contracted by the State or local government, and an employee of an organization of State or local officials having responsibility to facilitate harmonization of State or local standards and requirements in the Food and Drug Administration's areas of responsibility. For such officials, the statement and commitment required by paragraph (e)(1)(i) of this section shall be provided by both the organization and the individual.

■ 17. In § 20.89, revise paragraphs (d)(1) introductory text and (d)(1)(ii) to read as follows:

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) The Commissioner of Food and Drugs (or delegatee) may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other Government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

* * * * *

(ii) The Commissioner (or delegatee) makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

* * * * *

■ 18. In § 20.100:

■ a. Revise paragraph (c)(6);

■ b. Remove and reserve paragraphs (c)(20) and (21); and

■ c. Add paragraph (c)(48).

The revision and addition read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in §§ 108.25(k) and 108.35(l) of this chapter.

* * * * *

(48) Status reports of postmarketing study commitments in §§ 314.81(b)(2)(vii)(b) and 601.70(e) of this chapter.

■ 19. In § 20.120, revise paragraph (a) to read as follows:

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

(a) The Freedom of Information Staff and the Dockets Management Staff Public Reading Room are located at the same address. Both are located in Rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. The telephone number for the Docket Management Staff is 240–402–7500; the telephone number for the Freedom of Information Staff's Public Reading Room is located at the address on the Agency's website at *https://www.fda.gov.* Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

* * * * *

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

■ 20. The authority citation for part 720 continues to read as follows:

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

■ 21. In § 720.8, revise paragraphs (e) and (g) to read as follows:

§ 720.8 Confidentiality of statements.

* * * * *

(e) If, after receiving all of the data that are necessary to make a determination about whether the identity of an ingredient is a trade secret, FDA tentatively decides to deny the request, the Agency will inform the person requesting trade secrecy of its tentative determination in writing. FDA will set forth the grounds upon which it relied in making this tentative determination. The petitioner may submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the Agency reconsider its decision in light of both the additional material and the information that it originally submitted.

* * * * *

(g) A final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter constitutes final Agency action that is subject to judicial review under 5 U.S.C. Chapter 7. If suit is brought within 30 calendar days after such a determination, FDA will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts. If suit is not brought within 30 calendar days after a final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter, the records involved will be available for public disclosure in accordance with part 20 of this chapter.

Dated: August 31, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–19736 Filed 9–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0628]

Special Local Regulations; Marine Events Within the Seventh Coast Guard District

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Captain of the Port (COTP) Savannah, Georgia will enforce a special local regulation for the Ironman Triathlon in Augusta, Georgia, on September 25, 2022, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated area for this event in Augusta, GA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.701 will be enforced for the location identified in Section (d), Item 3 of Table 1 to § 100.701, from 6:30 a.m. until 10:30 a.m., on September 25, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, contact Coast Guard Marine Safety Unit Savannah, Office of Waterways Management, by calling or emailing MSTC Ashley Schad, telephone 912–652–4353 ext 242, or email *Ashley.M.Schad@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation in 33 CFR 100.701, Table 1 to § 100.701, Section (d), Item 3, for the Ironman Triathlon, from 6:30 a.m. to 10:30 a.m., on September 25, 2022.

This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District, 33 CFR 100.701, specifies the location of the regulated area for the Ironman Triathlon which encompasses portions of the Savannah River and its branches. During the enforcement periods, as reflected in 33 CFR 100.701(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

K.A. Broyles,

Commander, U.S. Coast Guard, Captain of the Port Savannah.

[FR Doc. 2022–19741 Filed 9–12–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0653]

Special Local Regulation; Marine Events Within the Eleventh Coast Guard District—San Diego Bayfair

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation on the waters of Mission Bay, CA, during the San Diego Bayfair on September 16, 2022, through September 18, 2022. This special local regulation is necessary to provide for the safety of the participants, crew, sponsor vessels of the event, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1101 for the location listed in Item 9 in table 1 to § 100.1101 will be enforced from 6 a.m. until 6 p.m., each day from September 16, 2022, through September 18, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Junior Grade Shera Kim, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the location identified in Item 9 in table 1 to § 100.1101, from 6 a.m. until 6 p.m., each day from September 16, 2022 through September 18, 2022, for the San Diego Bayfair in Mission Bay, CA. This action is being taken to provide for the safety of life on the navigable waterways during the event. Our regulation for recurring marine events in the San Diego Captain of the Port Zone, § 100.1101, Item No. 9 in table 1 to § 100.1101 specifies the location of the regulated area for the San Diego Bayfair, which encompasses portions of Mission Bay. Under the provisions of § 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area