**Authority:** 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.*

* * * * *

**AAL AK E5 Badami, AK [Amended]**

Badami, Badami Airport, AK
(Lat. 70°08′15″ N, long. 147°01′50″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Badami Airport, AK; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of Badami Airport, AK, excluding that airspace extending beyond 12 miles of the shoreline.

Issued in Seattle, Washington, on September 5, 2018.

**Shawn M. Kozica,**

*Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2018–19728 Filed 9–12–18; 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, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is proposing to amend its public information regulations. The proposed rule will revise 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 proposed rule will update the current regulations to reflect changes to the organization, to make the FOIA process easier for the public to navigate, and to make provisions clearer.

**DATES:** Submit either electronic or written comments on this proposed rule by November 13, 2018. See section VI of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions.'')

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2018–N–1622 for ''Public Information; Proposed Rule.'' Received comments, those received in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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 Proposed Rule*

FDA is proposing to amend FDA's public information regulations. The regulations are being amended to incorporate changes made to FOIA by the OPEN Government Act (Pub. L. 89–487) and the FOIA Improvement Act (Pub. L. 114–185). Additionally, the proposed rule will update the regulations to reflect changes to the organization, to make the FOIA process easier for the public to navigate, and to make certain provisions clearer. Taken together, these changes will enhance transparency for the public with regard to FDA activities.

### *B. Summary of the Major Provisions of the Proposed Rule*

The proposed 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*

We are proposing these amendments based on our authority under FOIA (5 U.S.C. 552) and section 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)). These proposed amendments would allow FDA to more efficiently use our 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 part 20 (21 CFR part 20). The revisions made by this proposed 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 rulemaking.

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

| Abbreviation/ Acronym | What it means |
|---|---|
| DFOI | Division of Freedom of Information. |
| 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 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 FOIA unless they are subject to one of nine FOIA exemptions. FDA's regulations for the implementation of the FOIA are in part 20. The FOIA Improvement Act 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

We are proposing these amendments based on our authority under FOIA (5 U.S.C. 552) and section 701(a) of the FD&C Act (21 U.S.C. 371(a)). These proposed amendments would allow FDA to more efficiently use our resources to provide information to the public.

## V. Description of the Proposed Rule

We are proposing to amend provisions of part 20 regarding the Agency's public information regulations. Once effective, the amendments contained in the proposed rule would apply to all FOIA requests currently pending with, or received in the future by, FDA.

- The proposed amendments to § 20.20 would 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 proposed 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 will 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 proposed amendment to § 20.22 would require 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 and was adopted by the Agency for FOIA processing as of the effective date of the OPEN Government Act.
- The proposed amendment to § 20.26 would require FDA to make available for public inspection in an electronic format records that have been requested three or more times 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 proposed amendment to § 20.33 would require FDA to offer the services of their FOIA Public Liaison and notify requesters of the services provided by the Office of Government Information Services (OGIS) when responding to FOIA requests. 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 proposed amendment to § 20.40 updates the provision to include reference to the Agency's online FOIA submission portal, which has been online since June 2012.
- The proposed amendments to § 20.41 would require that when FDA extends the time limit to respond to requests by more than 10 additional working days, FDA must notify the requester of the right to seek dispute resolution services from the FOIA Public Liaison and 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 to seek more information from the requester, and more than once (if necessary) to clarify fee assessments. This revision is required by the OPEN Government Act.

- The proposed amendment to § 20.44 updates the title of the Agency official making determinations regarding requests for expedited processing.
- The proposed amendments to § 20.45 would 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 will provide an incentive to the Agency to process requests as efficiently as possible, and will 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 proposed rule amends § 20.49(c) to require full and partial denial letters to include contact information for the FOIA Public Liaison and OGIS, and to increase the time for transmittal of an appeal to 90 business days. We also made technical revisions to § 20.49(a) to update the position title of the Agency FOIA Officer, and to § 20.49(c) to update the position title of the person to whom appeals shall be addressed. 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. These amendments are required by the FOIA Improvement Act.
- The proposed 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. This change will bring the Agency in line with departmental regulations.
- The proposed rule amends § 20.62 to prohibit the application of the deliberative process privilege of Exemption 5 of the FOIA to records created 25 years or more before the date on which the records were requested. This change will increase transparency by requiring the Agency to release information that could otherwise fall within the deliberative process privilege of the Exemption. This amendment is required by the FOIA Improvement Act.
- The amendment to § 20.82 clarifies that the discretionary disclosure standard outlined in that provision will guide the Agency's determinations of whether the Agency reasonably foresees that a disclosure of information would harm an interest protected by an exemption or disclosure is prohibited by law as required in administering § 20.20.
- The amendment to § 20.85 updates the statutory references.
- The amendment to § 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 § 20.89 remove references to position titles that no longer exist.
- The amendments to § 20.100 update the regulatory cross-references.
- The amendment to § 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 § 20.29.

## VI. Proposed Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

## VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed 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 upon FOIA requesters, including those that might be small entities, we propose to certify that the proposed 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 proposing ''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 $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We expect to incur 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 our routine practices for FOIA processing. The proposed rule, if finalized, would enhance public access to government information as required by the FOIA Improvement Act.

## VIII. 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.

## IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

**X. Federalism**

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed 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 proposed 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.

**XI. Consultation and Coordination With Indian Tribal Governments**

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively concluded that the rule does not contain policies that would have a substantial direct effect 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 a tribalism 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, we propose that 21 CFR parts 20 and 720 be 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 make discretionary disclosures of records or information exempt from disclosure under the provisions of this part whenever disclosure would not foreseeably harm an interest protected by an exemption pursuant to this part. This provision does not require disclosure of information that is prohibited from disclosure by law.

(c) In accordance with the FOIA Improvement Act of 2016 (Pub. L. 114–185), 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.

(d) Except as provided in paragraph (e) 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.

(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.

■ 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 paragraph (a)(4) to read as follows:

**§ 20.26 Electronic availability and 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 or that have been requested three or more times.

* * * * *

■ 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 FOIA Public Liaison and the Office of Government Information Services as required by the FOIA Improvement Act of 2016 (Pub. L. 114–185).

■ 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* or 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, revise paragraphs (b)(3)(i)(A) and (b)(4), and add paragraphs (b)(5) and (d) to 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 records to appeal any

adverse determination to the Deputy Agency Chief Freedom of Information Act Officer, Department of Health and Human Services, 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 necessary to respond 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 necessary to respond 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 (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 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 necessary to respond 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.

* * * * *

(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, revise paragraphs (a) and (c) and 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 other official who has been delegated the authority to release or withhold records.

* * * * *

(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 transmitted to the Deputy Agency Chief Freedom of Information Act Officer, Department of Health and Human Services, 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. 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.**

Inter-agency 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 shall make discretionary disclosures of records or information exempt from disclosure under the provisions of this part whenever disclosure would not foreseeably harm an interest protected by an exemption pursuant to this part. Specifically, 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 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 the 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. The 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 any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, 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, this provision does 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 any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, 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 his or her designee 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 this paragraph, 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 paragraph (d) to read as follows:

**§ 20.89 Communications with foreign government officials.**

* * * * *

(d)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, 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:

(i) The foreign 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 his or her designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

* * * * *

■ 18. In § 20.100, revise paragraph (c)(6), remove and reserve paragraphs (c)(20) and (21), and add paragraphs (c)(47) through (51).

The revision and additions 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.

* * * * *

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

(48) Postmarket notification relating to shortages in § 600.82 of this chapter.

(49) Postmarket notification relating to shortages in §§ 310.306 and 314.81 of this chapter.

(50) Minor Species/Minor Use designation, in § 516.52 of this chapter.

(51) Minor Species drug index listing, in § 516.171 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.

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## 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: September 7, 2018.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

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