

classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name vibratory counter-stimulation device, and it is identified as a

prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—VIBRATORY COUNTER-STIMULATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measure
Pain, discomfort, worsening of Restless Legs Syndrome symptoms	Non-clinical testing, Software testing, Labeling.
Electrical shock	Electrical safety testing, Labeling.
Burns	Electrical and thermal safety testing, Labeling.
Adverse skin reactions	Biocompatibility assessment, Labeling.
Interference with other medical devices	Electromagnetic compatibility testing, Labeling.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Vibratory counter-stimulation devices are not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that the device is not exempt from the premarket notification requirements of the FD&C Act. Persons who intend to market this type of device must submit a premarket notification (510(k)), prior to marketing the device, which contains information on the vibratory counter-stimulation device they intend to market.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in

part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 882.5895 to subpart F to read as follows:

§ 882.5895 Vibratory counter-stimulation device.

(a) *Identification.* A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC), electrical safety, and thermal safety.

(2) If the device contains software or firmware, appropriate verification, validation, and hazard analysis must be performed.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data (including vibration frequency, amplitude, and acceleration) must demonstrate that the device performs as

intended under anticipated conditions of use.

(5) Labeling must include:

(i) Specific information pertinent to use of the device by the intended patient population and the treatment regimen;

(ii) Warning to only use the device on normal, intact, clean, healthy skin;

(iii) Warning to not use the device if the user has leg skin disorders, such as eczema, psoriasis, cellulitis, non-healing wounds;

(iv) Warning to discontinue use if Restless Leg Syndrome symptoms worsen; and

(v) Instructions for end users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device.

Dated: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 802

RIN 3225–AA12

Revision of Regulations Governing Freedom of Information Act Requests

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Interim final rule.

SUMMARY: This interim final rule updates and clarifies the procedures for submitting Freedom of Information Act (FOIA) requests as required under the *FOIA Improvement Act of 2016* (the 2016 Act) which was signed into law by the President on June 30, 2016. This rule makes the procedural changes necessitated by the 2016 Act, including

requirements that agencies provide a minimum of 90 days for requesters to file an administrative appeal and that agencies provide dispute resolution services during the FOIA process. The 2016 Act also adds two new elements to agency Annual FOIA Reports. The rule codifies the “foreseeable harm” standard implemented by the 2016 Act. The principal changes that were required to the Court Services and Offender Supervision Agency for the District of Columbia’s (“CSOSA”) current regulations are discussed below.

Congress mandated that agencies make changes to their regulations within 180 days of the law taking effect. Because the changes are mandated by Congress and are non-controversial, CSOSA is publishing this rule as an interim final rule.

DATES: This interim final rule is effective March 14, 2017.

FOR FURTHER INFORMATION CONTACT: Sheila Stokes, General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Ave. NW., Room 1380, Washington, DC 20004; telephone: 202–220–5797; email: Sheila.stokes@csosa.gov.

SUPPLEMENTARY INFORMATION: The 2016 Act (Pub. L. 114–185) required agencies to update their regulations on FOIA compliance. The 2016 Act addresses procedural issues to help improve the FOIA process across all Federal agencies. It requires agencies to establish a minimum of 90 days for requesters to file administrative appeals, to establish additional dispute resolution services, and to codify the Department of Justice’s “foreseeable harm” standard, which only allows agencies to withhold information if the agency reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or the disclosure is prohibited by law.

CSOSA was established within the Executive Branch of the Federal Government by the *National Capital Revitalization and Self-Government Improvement Act of 1997*, Public Law 105–33, 111 Stat. 251, 712 (D.C. Code 24–1232, 24–1233). On August 4, 2000, CSOSA was certified by the Attorney General as an independent Federal agency.

CSOSA is amending its regulations on the process for requesting information under the Freedom of Information Act to comply with the 2016 Act. This includes the process for requests to the District of Columbia Pretrial Services Agency (“PSA”), an independent entity within CSOSA. CSOSA provides supervisory and treatment services to

individuals on probation, parole, and supervised release for District of Columbia Code violations. CSOSA also provides supervisory and treatment services to offenders from other jurisdictions in accordance with the Interstate Parole and Probation Compact. PSA supervises, monitors, and provides treatment services to defendants in the U.S. District Court and the United States Court of Appeals for the District of Columbia Circuit and to individuals on pretrial release for District of Columbia Code violations.

I. Background

CSOSA is revising its FOIA regulations to comply with the 2016 Act. The following is a description of the changes.

CSOSA has updated its regulations at § 802.1 to provide additional information about the FOIA process at CSOSA.

CSOSA has updated its regulations at § 802.2 to include a designation of its Chief FOIA Officer and statement that the Chief FOIA Officer will be responsible for naming the FOIA Public Liaison.

CSOSA has updated its regulations by adding a new § 802.3 and renumbering the remaining sections. The new § 802.3 reinforces CSOSA’s commitment to transparency and explains what information and records are available for public inspection. It also speaks to the preservation of records during a request, appeal, or lawsuit under FOIA and CSOSA’s disposition and destruction schedule as allowed by the National Archives and Records Administration.

In the renumbered new § 802.4 CSOSA, which discusses the guidelines for disclosure, added information on the applicable exemptions and/or exclusions to disclosure.

In the renumbered new § 802.5 CSOSA added an additional definition.

In the renumbered new § 802.6 CSOSA inserted information about the new FOIA Public Liaison, its role, and the ability to seek dispute resolution from the Office of Government Information Services. In addition, CSOSA added directions for requesting information, the timelines for the release of information, and waiver of fee requests. CSOSA added information about requests for modifications, denials, and exceptional circumstances for agency non-compliance with deadlines set by law. CSOSA also added information about withholding information due to foreseeable harm, a standard that was codified by the 2016 Act. Finally, CSOSA added information about how requesters can file

administrative appeals of agency decisions.

The old § 802.7 was deleted. In the new § 802.7 CSOSA inserted information of what occurs if the documents requested were created more than 25 years prior to the request for information and how CSOSA staff should handle requests for non-Federal agency records that are part of CSOSA records.

In § 802.8 CSOSA added information about expedited processing and how to determine if there is a compelling need for expediting processing.

The new fee provisions of the 2016 Act were incorporated into § 802.10, which include the inability of an agency to assign any search fees if it has failed to follow the deadlines set by the law. Unusual circumstances where more than 5,000 pages are required to comply with the request, fees may be charged by an agency if timely notice is supplied to the requestor. Any court actions may excuse any timeliness issues if a court sets its own time frames.

II. Procedural Issues and Regulatory Review

Administrative Procedure Act (APA): This action is taken under the requirements of the *FOIA Improvement Act of 2016*, Public Law 114–185, to publish regulations complying with the law by December 30, 2016 in the **Federal Register**. Because this rule pertains to explicit changes mandated by Congress, CSOSA is issuing the rule as final without general notice of proposed rulemaking and without any delay in its effectiveness. Any interested person, however, who wishes to submit comments on the rule may do so by writing or emailing the agency at the addresses given above in the **FOR FURTHER INFORMATION CONTACT** caption.

Executive Order 12866 and 13563 (Regulatory Planning and Review): CSOSA does not anticipate that this interim final rule will have significant economic impact, raise novel issues, and/or have any other significant impacts because it simply incorporates the provisions of the *FOIA Improvement Act of 2016* into the current CSOSA FOIA regulations. Thus this interim final rule is not a significant regulatory action under 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under 6(a)(3) of the Order.

Regulatory Flexibility Act (RFA): The Regulatory Flexibility Act does not apply. This interim final rule will not directly regulate small entities. CSOSA, therefore, does not need to perform a regulatory flexibility analysis of small entity impacts.

Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA): CSOSA has determined that this interim final rule does not impose a significant impact on a substantial number of small entities under the RFA; therefore, CSOSA is not required to produce any Compliance Guides for Small Entities as mandated by the SBREFA.

Congressional Review Act: CSOSA has determined that this interim final rule is not a major rule under the Congressional Review Act, as it is unlikely to result in an annual effect on the economy of \$100 million or more; is unlikely to result in a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies or geographic regions; and is unlikely to have a significant adverse effect on competition, employment, investment, productivity, or innovation, or on the ability of U.S.-based enterprises to compete in domestic and export markets.

Unfunded Mandates Reform Act (UMRA): This revision does not impose any federal mandates on state, local, or tribal governments, or on the private sector within the meaning of the UMRA.

National Environmental Policy Act (NEPA): This interim final rule will have no physical impact upon the environment and, therefore, will not require any further review under NEPA.

Paperwork Reduction Act (PRA): The Paperwork Reduction Act does not apply because the rule does not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

Executive Order 13132 (Federalism): This final revision does not have new federalism implications under Executive Order 13132.

Executive Order 12988 (Civil Justice Reform): This interim final rule meets applicable standards of 3(a) and 3(b)(2) of Executive Order 12988 and CSOSA has determined that the interim final rule will not unduly burden the Federal court system.

Plain Language: E.O. 12866 and E.O. 13563 require regulations to be written in a manner that is easy to understand. CSOSA has concluded that it has drafted this interim final rule in plain language.

Assessment of Federal Regulations and Policies on Families: Section 654 of the *Treasury and General Government Appropriations Act*, enacted as part of the *Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999* (Pub. L. 105–277, 112 Stat. 2681) requires the

assessment of the impact of this rule on family well-being. CSOSA has assessed this interim final rule and determined that the rule will not have a negative effect on families.

Executive Order 13175 (Indian Tribal Governments): CSOSA reviewed this interim final rule under the terms of E.O. 13175 and has determined that the rule will not have tribal implications.

Executive Order 12630 (Government Actions and Interference With Constitutionally Protected Property Rights): CSOSA has determined that this interim final rule is not subject to E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

Executive Order 13211 (Energy Supply): This CSOSA interim final rule was drafted and reviewed in accordance with E.O. 13211, Energy Supply. CSOSA has determined that this interim final rule will not have a significant adverse effect on the supply, distribution, or use of energy and is not subject to E.O. 13211.

List of Subjects in 28 CFR Part 802

Administrative practice and procedure, Freedom of information, Government employees, Privacy, Probation and parole.

Authority and Issuance

For the reasons stated in the preamble, the Court Services and Offender Supervision Agency for the District of Columbia amends 28 CFR part 802 as set forth below:

PART 802—DISCLOSURE OF RECORDS

- 1. Revise the authority citation for part 802 to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; Pub. L. 105–33, 111 Stat. 251, 712 (DC Code 24–1232, 24–1233); Pub. L. 114–185, 130 Stat. 538 (Jun. 30, 2016).

- 2. Revise § 802.1 to read as follows:

§ 802.1 Introduction.

(a) This part contains regulations of the Court Services and Offender Supervision Agency for the District of Columbia (“CSOSA” or “Agency”) and the District of Columbia Pretrial Services Agency (“PSA” or “Agency”), which implement the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Privacy Act (PA), 5 U.S.C. 552a. The Agency provides for the disclosure and production of records in response to FOIA/PA requests, a demand from a court, or other non-congressional authority in connection with a

proceeding to which the Agency is not a party. Due to CSOSA’s nature as a federal agency with a local mission connected to the District of Columbia, exemption protections, including exclusions, are allowed under the FOIA and other safeguard requirements may be applied under the PA.

(b) It is the policy of CSOSA that all employees of CSOSA and PSA (collectively the “Agency”) are to submit all FOIA/PA requests to the Office of General Counsel (“OGC”). The OGC shall make release determinations under either the FOIA/PA pursuant to the procedures set forth in sections §§ 802.6, 802.7, 802.8, 802.14, 802.15, and 802.16.

- 3. Revise subpart B to read as follows:

Subpart B—Freedom of Information Act

Sec.

- 802.2 Purpose and scope.
- 802.3 Information and records for public inspection.
- 802.4 Guidelines for disclosure.
- 802.5 Definitions.
- 802.6 Freedom of Information Act requests.
- 802.7 Documents from other agencies.
- 802.8 Expedited processing.
- 802.9 Business information.
- 802.10 Fee schedule.

§ 802.2 Purpose and scope.

(a) The purpose of this subpart is to establish procedures for the release of records in the custody, possession or control of the Agency pursuant to the provisions of the FOIA as amended by the *FOIA Improvement Act of 2016* (Pub. L. 114–185).

(b) The Director of CSOSA has designated the General Counsel to be the Chief FOIA Officer as defined in 5 U.S.C. 552(j).

(c) The Chief FOIA Officer shall designate at least one FOIA Public Liaison as defined in 5 U.S.C. 552(j)(2)(H) and 552(l) for assisting in reducing delays, increasing transparency, understanding the status of requests, and assisting in the resolution of disputes.

§ 802.3 Information and records for public inspection.

(a) *Public inspection.* In accordance with this section, CSOSA makes the following information and materials available for public inspection pursuant to 5 U.S.C. 552:

(1) The Agency’s publications in the **Federal Register** for the guidance of the public.

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

(3) The Agency's policy statements that have been adopted by the Agency and are not published in the **Federal Register**.

(4) Administrative staff manuals and instructions to staff that affect a member of the public.

(5) Copies of all records, regardless of format, that have become or are likely to become the subject of subsequent requests for substantially the same records or have been requested three or more times; and these available records exclude first party requests.

(6) Reports available for public inspection shall be available:

- (i) In a timely manner;
- (ii) With raw statistical data in electronic format;
- (iii) In a general index;
- (iv) Without charge, license, or registration requirement;
- (v) In an aggregated, searchable format;
- (vi) In a format that may be downloaded in bulk; and
- (vii) Which include, but are not limited to the:

- (A) Chief FOIA Officer Report;
- (B) Annual FOIA Report; and
- (C) Quarterly FOIA Report.

(7) An index of all major information systems of the agency.

(8) A description of major information and record locator systems maintained by the agency.

(9) A handbook for obtaining various types of categories of public information from the Agency pursuant to chapter 35 of Title 44 of the United States Code, and under this section.

(b) *Preservation of records.* (1) All agency correspondence as well as copies of all requested records shall be preserved until disposition or destruction is authorized pursuant to Title 44 of the United States Code or the General Records Schedule 4.2 of the National Archives and Records Administration (NARA).

(2) The agency will not dispose of or destroy records while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

§ 802.4 Guidelines for disclosure.

(a) The authority to release, partially release, or deny access to records and information under the FOIA is limited to the Chief FOIA Officer, FOIA Public Liaison, and his or her designee.

(b) An Agency record will be released in response to a written request, unless a valid legal exemption and/or exclusion to disclosure is asserted.

(1) Any applicable exemption and/or exclusion to disclosure, which is provided under the FOIA in 5 U.S.C. 552, may be asserted. The applicable

exemptions and/or exclusions to disclosure are as follows:

(i) *Exclusions.* (A) Where the subject of a criminal investigation or proceeding is unaware of the existence of records concerning a pending investigation and disclosure of such records would interfere with the investigation.

(B) Where there are informant records maintained by a criminal law enforcement agency and the individual's status as an informant is not known.

(C) Where there are classified FBI records pertaining to foreign intelligence, counterintelligence or international terrorism records.

(ii) *Exemptions.* (A) Information that is classified to protect national security.

(B) Information related solely to the internal personnel rules and practices of an agency.

(C) Information that is prohibited from disclosure by another federal law.

(D) Trade secrets or commercial or financial information that is confidential or privileged.

(E) Privileged communications within or between agencies, including:

- (1) Deliberative process privilege;
- (2) Attorney-work product privilege; and

(3) Attorney-client privilege.

(F) Information that, if disclosed, would invade another individual's personal privacy.

(G) Information compiled for law enforcement purposes that:

- (1) Could reasonably be expected to interfere with enforcement proceedings.
- (2) Would deprive a person of a right to a fair trial or an impartial adjudication.

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy.

(4) Could reasonably be expected to disclose the identity of a confidential source.

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions.

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(H) Information that concerns the supervision of financial institutions.

(I) Geological information on wells.

(2) A record must exist and be in the possession and control of the Agency at the time of the request to be considered subject to this part and the FOIA. There is no obligation to create, compile, or obtain a record to satisfy a FOIA request.

§ 802.5 Definitions.

As used in this subpart, the following terms have the following meanings:

(a) *Agency* has the meaning given in 5 U.S.C. 551(1) and 5 U.S.C. 552(f).

(b) *Appeal* means a request for a review of the agency's determination with regard to a fee waiver, category of requester, expedited processing, or denial in whole or in part of a request for access to a record or records.

(c) *Business information* means trade secrets or other commercial or financial information.

(d) *Business submitter* means any entity which provides business information to the Agency and which has a proprietary interest in the information.

(e) *Computer software* means tools by which records are created, stored, and retrieved. Normally, computer software, including source code, object code, and listings of source and object codes, regardless of medium, are not agency records. Proprietary (or copyrighted) software is not an agency record.

(f) *Confidential commercial information* means records provided to the government by a submitter that arguably contain material exempt from release under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm.

(g) *Duplication* refers to the process of making a copy of a record in order to respond to a FOIA request. Such copies can take the form of paper copy, microform, audio-visual materials, or machine-readable documentation (e.g., magnetic tape or disk), among others.

(h) *Electronic records* mean those records and information which are created, stored, and retrievable by electronic means. This ordinarily does not include computer software, which is a tool by which to create, store, or retrieve electronic records.

(i) *Record* is defined pursuant to 44 U.S.C. 3301.

(j) *Request* means any request for records made pursuant to 5 U.S.C. 552(a)(3).

(k) *Requester* means any person who makes a request for access to records.

(l) *Review* for fee purposes, refers to the process of examining records located in response to a commercial use request to determine whether any portion of any record located is permitted to be withheld. It also includes processing any records for disclosure; e.g., doing all that is necessary to excise them and otherwise prepare them for release.

(m) *Search* includes all time spent looking for material that is responsive to a request, including page-by-page or line-by-line identification of material

within records. Searches may be done manually or by automated means.

§ 802.6 Freedom of Information Act requests.

(a) *Submission and processing procedures.*(1) Requests for any record (including policy) ordinarily will be processed pursuant to the Freedom of Information Act, 5 U.S.C. 552. Your request must be made in writing and addressed to the FOIA Public Liaison Officer, Office of the General Counsel FOIA Office, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue NW., 12th Floor, Washington, DC 20004. The requester should clearly mark on the face of the letter and the envelope "Freedom of Information Act Request."

(2) Your request will be considered received as of the date it is received by CSOSA's FOIA Office.

(3) Generally, all FOIA requests will be processed in the approximate order of receipt, unless the requester shows exceptional circumstances exist to justify an expedited response (*see* § 802.8).

(4) You must describe the records that you seek in enough detail to enable Agency personnel to locate them with a reasonable amount of effort. Whenever possible, your request should include specific information about each record sought, such as the date, title or name, author, recipient and subject matter of the record. As a general rule, the more specific you are about the records or type of records that you want, the more likely the Agency will be able to locate the records in response to your request. If a determination is made that your request does not reasonably describe records, the Agency will tell you either what additional information is needed or why your request is otherwise insufficient. You will be given the opportunity to discuss your request so that you may modify it to meet the requirements of this section.

(5)(i) *Requests by offender/defendant for offender's records.* (A) An offender/defendant making a FOIA/PA request must provide his or her full name, current address, and date of birth. In addition, the requester must provide with the request his or her signature, which must be either notarized or sworn under penalty of perjury pursuant to 28 U.S.C. 1746, and dated within three (3) months of the date of the request.

(B) To assist in properly identifying requested records, the OGC and/or FOIA Office may request that the offender/defendant provide his/her DCDC or PDID number.

(ii) *Requests for offender records on behalf of an offender/defendant.* (A) A request for records made by an authorized representative of an offender/defendant will only be released with the subject's written authorization with appropriate releases. This authorization and releases must be dated within thirty (30) days of the date of the request letter and must be signed by the offender/defendant.

(B) To assist in properly identifying requested records, the OGC and/or FOIA Office may request that the offender/defendant provided his/her DCDC or PDID number.

(6) You must state in your request a firm agreement to pay the fees for search, duplication, and review as may ultimately be determined. The agreement may state the upper limit (but not less than \$10.00) that the requester is willing to pay for processing the request. A request that fees be waived or reduced may accompany the agreement to pay fees and will be considered to the extent that such request is made in accordance with § 802.4(b) and provides supporting information to be measured against the fee waiver standard set forth in § 802.9(g). The requester shall be notified in writing of the decision to grant or deny the fee waiver. If a requester has an outstanding balance of search, review, or duplication fees due for FOIA request processing, the requirements of this paragraph (a)(6) are not met until the requester has remitted the outstanding balance due.

(b) *Release determination*—(1) *Notification.* You will be notified of the decision on the request within twenty (20) days after its receipt (excluding Saturdays, Sundays, and legal public holidays).

(i) The twenty (20) day period shall be tolled if:

(A) The Agency needs clarification and/or more information from the requester; or

(B) Clarification is needed with the requester regarding fee assessment.

(C) The agency's receipt of the requester's response to the agency's request for information or clarification ends the tolling period.

(ii) The twenty (20) day period shall be extended for ten (10) additional working days with written notice to the requester for unusual circumstances.

(A) Unusual circumstances means, but only to the extent reasonably necessary to the proper processing of particular requests—

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(B) The written notice to the requester for unusual circumstances shall:

(1) Notify the person making the request if the request cannot be processed within the time limit specified;

(2) Provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request;

(3) Make available the Agency's FOIA Public Liaison Officer, who shall assist in the resolution of any disputes between the requester the Agency; and

(4) Notify the requester of the right of the requester to seek dispute resolution services from the Office of Government Information Services.

(iii) When the Agency fails to comply with the applicable time limit provisions of paragraph (b) of this section, if the Agency can show exceptional circumstances exist and that the Agency is exercising due diligence in responding to the request, the Agency may be allowed additional time to complete its review of the records.

(A) For purposes of this paragraph (b)(1)(iii), the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

(B) Refusal by a person to reasonably modify the scope of a request or arrange an alternative time frame for processing a request (or a modified request) after being given an opportunity to do so by the Agency to whom the person made the request shall be considered as a factor in determining whether exceptional circumstances exist for purposes of this paragraph (b)(1)(iii).

(2) *Denial in whole or in part.* If it is determined that the request for records should be denied in whole or in part, the requester shall be notified by mail with a letter stating the basis for partial or whole denial. The letter of notification shall:

(i) Be signed by the Chief FOIA Officer or his or her designee;

(ii) State the exemptions relied on to not release the information;

(A) Advise the requester of the reason of adverse determination and the right to administrative appeal in accordance with paragraph (c) of this section;

(B) Advise the right of such person to seek assistance from the FOIA Public Liaison Officer of the agency; and

(C) Advise the right of such person to seek assistance from the Office of Government Information Services;

(iii) If technically feasible, indicate the amount of information deleted at the place in the record where such deletion is made (unless providing such indication would harm an interest protected by the exemption relied upon to deny such material);

(iv) If a document contains information exempt from disclosure, any reasonably segregable portion of the record will be provided to you after deletion of the exempt portions;

(v) An agency shall—

(A) Withhold information under this section only if—

(1) The agency reasonably foresees that disclosure would harm an interest protected by an exemption described in paragraph (b) of this section; or

(2) Disclosure is prohibited by law; and

(B) Partially withhold information under this section only if—

(1) Partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible; and

(2) Take reasonable steps necessary to segregate and release nonexempt information; and

(vi) Nothing in this paragraph (b)(2) requires disclosure of information that is otherwise prohibited from disclosure by law, or otherwise exempted from disclosure by statute.

(3) *No records found.* If it is determined, after a thorough search for records by the responsible official or his delegate, that no records have been found to exist, the Chief FOIA Officer or his/her designee will so notify the requester in writing. The letter of notification will advise the requester of his or her right to administratively appeal within ninety (90) of the determination that no records exist (*i.e.*, to challenge the adequacy of the search for responsive records) in accordance with paragraph (c) of this section. The response shall specify the official or office to which the appeal shall be submitted for review.

(c) *Administrative appeal.* (1) A requester may appeal an initial determination when:

(i) Access to records has been denied in whole or in part;

(ii) There has been an adverse determination of the requester's category as provided in § 802.10(d);

(iii) Inadequacy of the FOIA search;

(iv) A request for fee waiver or reduction has been denied; or

(v) It has been determined that no responsive records exist.

(2) Appeals must be made within ninety (90) days of the receipt of the letter with an adverse determination. Both the envelope and the letter of appeal should be sent to the Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue NW., 13th Floor, Washington, DC 20004 and must be clearly marked "Freedom of Information Act (FOIA) Appeal."

(3) The General Counsel will make an appeal determination within twenty (20) days (excluding Saturdays, Sundays, and holidays) from the date of receipt of the appeal. However, for a good reason, this time limit may be extended up to an additional ten (10) days. If, after review, the General Counsel determines that additional information should be released, it will accompany the appeal response. If, after review, the General Counsel determines to uphold the initial review, we will inform you.

§ 802.7 Documents from other agencies.

(a) *Documents from or relating to Federal agencies.* (1) When a request for records includes a document that originated from another Federal agency, the document will be referred to the originating Federal agency for release determination, unless the information requested is for records created 25 years or more before the date on which the records were requested, in which case CSOSA will release them without referral and/or consultation with the other federal agency. The requester will be informed of the referral. This is not a denial of a FOIA request; thus, no appeal rights accrue to the requester.

(2) When a FOIA request is received for a record created by the Agency that includes information by another Federal agency, the record will be sent to the other Federal agency that has equities in the record. The consultation will request that the other Federal agency review and provide recommendations on disclosure. The Agency will not release any such record without prior consultation with the other Federal agency that has equities in the record.

(b) *Documents from non-Federal agencies.* When a request for records includes a document from a non-Federal

agency, CSOSA staff must make a release determination.

(1) A release determination on the records from non-Federal agencies shall be analyzed on a case-by-case to determine if CSOSA or the non-Federal agency is best able to decide a record's sensitivity, and in turn its exemption status, in which case:

(i) The requester will be re-routed to submit a separate FOIA request to the non-Federal agency; or

(ii) CSOSA will consult with the non-Federal agency only if the non-Federal agency will provide a consultation within five (5) business days.

(2) [Reserved]

§ 802.8 Expedited processing.

(a) Requests and appeals will be taken out of order and given expedited treatment whenever CSOSA's FOIA Office determines that they involve:

(1) Circumstances in which the person requesting the records demonstrates a compelling need.

(i) For purposes of this paragraph (a)(1), the term "compelling need" means—

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

(B) A person is primarily engaged in disseminating information and the urgency to inform the public concerning actual or alleged Federal Government activity is a matter of widespread and exceptional media interest in which there exist possible questions about the government's integrity.

(1) With respect to a request made by a person primarily engaged in disseminating information that affect public confidence, the requester must adequately explain the matter or activity and why it is necessary to provide the records being sought on an expedited basis.

(i) A person "primarily engaged in disseminating information" does not include individuals who are engaged only incidentally in the dissemination of information.

(ii) The standard of "widespread and exceptional media interest" requires that the records requested pertain to a matter of current exigency to the American public and that delaying a response to a request for records would compromise a significant recognized interest to and throughout the general public. The requester must adequately explain the matter or activity and why it is necessary to provide the records being sought on an expedited basis.

(2) [Reserved]

(ii) [Reserved]

(2) [Reserved]

(b) If a requester seeks expedited processing, the requester must submit a statement, certified to be true and correct to the best of your knowledge and belief. The statement must be in the form prescribed by 28 U.S.C. 1746, "I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. Executed on [date]."

(c) The determination as to whether to grant or deny the request for expedited processing will be made, and the requester notified, within ten (10) days after the date of the request. Because a decision to take a FOIA request out of order delays other requests, simple fairness demands that such a decision be made by the FOIA Public Liaison Officer only upon careful scrutiny of truly exceptional circumstances. The decision will be made solely based on the information contained in the initial letter requesting expedited processing.

(d) Appeals of initial determinations to deny expedited processing must be made promptly. Both the envelope and the letter of appeal should be sent to the Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Avenue NW., 12th Floor, Washington, DC 20004 and must be clearly marked "Expedited Processing Appeal."

(e) The OGC or his or designee will make an appeal determination regarding expedited processing as soon as practicable.

§ 802.9 Business information.

(a) *In general.* Business information provided to the Agency by a business submitter will be disclosed pursuant to the FOIA, unless exemptions and/or exclusions apply. Any claim of confidentiality must be supported by a statement by an authorized representative of the company providing specific justification that the information in question is in fact confidential commercial or financial information and has not been disclosed to the public.

(b) *Notice to business submitters.* The Agency will provide a business submitter with prompt written notice of receipt of a request or appeal encompassing its business information whenever required in accordance with paragraph (c) of this section, and except as is provided in paragraph (g) of this section. Such written notice shall either describe the exact nature of the business information requested or provide copies of the records or portions of records containing the business information.

(c) *When notice is required.* (1) Notice of a request for business information falling within paragraph (c)(2)(i) or (ii) of this section will be required for a period of not more than ten years after the date of submission unless the business submitter had requested, and provided acceptable justification for, a specific notice period of greater duration.

(2) The Agency shall provide a business submitter with notice of receipt of a request or appeal whenever:

(i) The business submitter has in good faith designated the information as commercially or financially sensitive information; or

(ii) The Agency has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

(d) *Opportunity to object to disclosure.* (1) Through the notice described in paragraph (b) of this section, the Agency shall afford a business submitter ten (10) days from the date of the notice (exclusive of Saturdays, Sundays, and legal public holidays) to provide a detailed statement of any objection to disclosure. Such statement shall specify why the business submitter believes the information is considered to be a trade secret or commercial or financial information that is privileged or confidential. Information provided by a business submitter pursuant to this paragraph might itself be subject to disclosure under the FOIA.

(2) When notice is given to a submitter under this section, the requester shall be advised that such notice has been given to the submitter. The requester shall be further advised that a delay in responding to the request may be considered a denial of access to records and that the requester may proceed with an administrative appeal or seek judicial review, if appropriate. However, the requester will be invited to agree to a voluntary extension of time so that staff may review the business submitter's objection to disclose.

(e) *Notice of intent to disclose.* The Agency will consider carefully a business submitter's objections and specific grounds for nondisclosure prior to determining whether to disclose business information. Whenever a decision to disclose business information over the objection of a business submitter is made, the Agency shall forward to the business submitter a written notice which shall include:

(1) A statement of the reasons for which the business submitter's disclosure objections were not sustained;

(2) A description of the business information to be disclosed; and

(3) A specified disclosure date which is not less than five (5) days (exclusive of Saturdays, Sundays, and legal public holidays) after the notice of the final decision to release the requested information has been mailed to the submitter.

(f) *Notice of FOIA lawsuit.* Whenever a requester brings suit seeking to compel disclosure of business information covered by paragraph (c) of this section, the Agency shall promptly notify the business submitter.

(g) *Exception to notice requirement.* The notice requirements of this section shall not apply if:

(1) The Agency determines that the information shall not be disclosed;

(2) The information lawfully has been published or otherwise made available to the public; or

(3) Disclosure of the information is required by law (other than 5 U.S.C. 552).

§ 802.10 Fee schedule.

(a) *Fees.* The fees described in this section conform to the Office of Management and Budget Uniform Freedom of Information Act Fee Schedule and Guidelines. They reflect direct costs for search, review (in the case of commercial requesters), and duplication of documents, collection of which is permitted by the FOIA. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given below or for other reasons.

(b) *Types of cost.* The term *direct costs* means those expenditures the agency actually makes in searching for, review (in the case of commercial requesters), and duplicating documents to respond to a FOIA request.

(c) *Types of fees.* Fees shall be charged in accordance with the schedule contained in paragraph (i) of this section for services rendered in responding to requests for records, unless any one of the following applies:

(1) Services were performed without charge; or

(2) The fees were waived or reduced in accordance with paragraph (f) of this section.

(d) *Categories of fees.* Specific levels of fees are prescribed for each of the following categories of requesters:

(1) *Commercial use requesters.* These requesters are assessed charges, which recover the full direct costs of searching for, reviewing, and duplicating the records sought. Commercial use requesters are not entitled to two hours of free search time or 100 free pages of duplication of documents. Moreover,

when a request is received for disclosure that is primarily in the commercial interest of the requester, the Agency is not required to consider a request for a waiver or reduction of fees based upon the assertion that disclosure would be in the public interest. The Agency may recover the cost of searching for and reviewing records even if there is ultimately no disclosure of records, or no records are located.

(2) *Educational and non-commercial scientific institution requesters.* Records shall be provided to requesters in these categories for the cost of duplication alone, excluding charges for the first 100 pages. To be eligible, requesters must show that the request is made under the auspices of a qualifying institution and that the records are not sought for a commercial use, but are sought in furtherance of scholarly (if the request is from an educational institution) or scientific (if the request is from a non-commercial scientific institution) research. These categories do not include requesters who want records for use in meeting individual academic research or study requirements.

(3) *Requesters who are representatives of the news media.* Records shall be provided to requesters in this category for the cost of duplication alone, excluding charges for the first 100 pages.

(4) *All other requesters.* Requesters who do not fit any of the categories described in paragraphs (d)(1) through (3) of this section shall be charged fees that will recover the full direct cost of searching for and duplicating records that are responsive to the request, except that the first 100 pages of duplication and the first two hours of search time shall be furnished without charge. The Agency may recover the cost of searching for records even if there is ultimately no disclosure of records, or no records are located. Requests from persons for records about themselves filed in a systems of records shall continue to be treated under the fee provisions of the Privacy Act of 1974 which permit fees only for duplication.

(e) *Fee waiver determination.* Where the initial request includes a request for reduction or waiver of fees, the responsible official shall determine whether to grant the request for reduction or waiver before processing the request and notify the requester of this decision. If the decision does not waive all fees, the responsible official shall advise the requester of the fact that fees shall be assessed and, if applicable, payment must be made in advance pursuant to paragraph (g) of this section.

(f) *Waiver or reduction of fees.* (1) Fees may be waived or reduced on a

case-by-case basis in accordance with this paragraph (f)(1) by the official who determines the availability of the records, provided such waiver or reduction has been requested in writing. Fees shall be waived or reduced by this official when it is determined, based upon the submission of the requester, that a waiver or reduction of the fees is in the public interest because furnishing the information is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester. Fee waiver/reduction requests shall be evaluated against the current fee waiver policy guidance issued by the Department of Justice.

(2) Appeals from denials of requests for waiver or reduction of fees shall be decided in accordance with the criteria set forth in this section by the official authorized to decide appeals from denials of access to records. Appeals shall be addressed in writing to the Office of the General Counsel, Court Services and Offender Supervision Agency for the District of Columbia, Office of the General Counsel, 633 Indiana Avenue NW., 13th Floor, Washington, DC 20004 within thirty (30) days of the denial of the initial request for waiver or reduction and shall be decided within twenty (20) days (excluding Saturdays, Sundays and holidays).

(3) Appeals from an adverse determination of the requester's category as described in paragraphs (d)(1) through (3) of this section shall be decided by the official authorized to decide appeals from denials of access to records and shall be based upon a review of the requester's submission and the Agency's own records. Appeals shall be addressed in writing to the office or officer specified in paragraph (d)(2) of this section within thirty (30) days of the receipt of the Agency's determination of the requester's category and shall be decided within twenty (20) days (excluding Saturdays, Sundays, and holidays).

(g) *Advance notice of fees.* (1) When the fees for processing the request are estimated to exceed the limit set by the requester, and that amount is less than \$250.00, the requester shall be notified of the estimated costs. The requester must provide an agreement to pay the estimated costs; however, the requester will also be given an opportunity to reformulate the request in an attempt to reduce fees.

(2) If the requester has failed to state a limit and the costs are estimated to exceed \$250.00, the requester shall be notified of the estimated costs and must

pre-pay such amount prior to the processing of the request, or provide satisfactory assurance of full payment if the requester has a history of prompt payment of FOIA fees. The requester will also be given an opportunity to reformulate the request in an attempt to reduce fees.

(h) *Form of payment.* (1) Payment may be made by check or money order payable to the Treasury of the United States.

(2) The Agency reserves the right to request prepayment after a request is processed and before documents are released in the following circumstances.

(i) When costs are estimated or determined to exceed \$250.00, the Agency shall either obtain satisfactory assurance of full payment of the estimated cost where the requester has a history of prompt payment of FOIA fees or require the requester to make an advance payment of the entire estimated or determined fee before continuing to process the request.

(ii) If a requester has previously failed to pay a fee within thirty (30) days of the date of the billing, the requester shall be required to pay the full amount owed plus any applicable interest, and to make an advance payment of the full amount of the estimated fee before the Agency begins to process a new request or the pending request. Whenever interest is charged, the Agency shall begin assessing interest on the 31st day following the day on which billing was sent. Interest shall be at the rate prescribed in 31 U.S.C. 3717.

(i) *Amounts to be charged for specific services.* The fees for services performed by an employee of the Agency shall be imposed and collected as set forth in this paragraph (i).

(1) *Duplicating records.* All requesters, except commercial requesters, shall receive the first 100 pages duplicated without charge; the first two hours of search time free; or charge which total \$10.00 or less. Fees for the copies are to be calculated as follows:

(i) The duplication cost is calculated by multiplying the number of pages in excess of 100 by \$0.25.

(ii) Photographs, films, and other materials—actual cost of duplication.

(iii) Other types of duplication services not mentioned above—actual cost.

(iv) Material provided to a private contractor for copying shall be charged to the requester at the actual cost charged by the private contractor.

(2) *Search services.* The cost of search time is calculated by multiplying the number of quarter hours in excess of

two hours by the following rates for the staff conducting the search:

(i) \$7.00 per quarter hour for clerical staff;

(ii) \$10.00 per quarter hour for professional staff; and

(iii) \$14.00 per quarter hour for managerial personnel.

(3) *Only fees in excess of \$10.00 will be assessed.* This means that the total cost must be greater than \$10.00, either for the cost of the search (for time in excess of two hours), for the cost of duplication (for pages in excess of 100), or for both costs combined.

(j) *Searches for electronic records.* The Agency shall charge for actual direct cost of the search, including computer search time, runs, and the operator's salary. The fee for computer output shall be actual direct costs. For requesters in the "all other" category, when the cost of the search (including the operator time and the cost of operating the computer to process a request) equals the equivalent dollar amount of two hours of the salary of the person performing the search (*i.e.*, the operator), the charge for the computer search will begin.

(k) *Aggregating requests.* When the Agency reasonably believes that a requester or group of requesters is attempting to break a request down into a series of requests for the purpose of evading the assessment of fees, the Agency shall aggregate any such requests and charge accordingly.

(l) The agency shall not assess any search fees (or in the case of an educational or noncommercial scientific institution, or a representative of the news media—duplication fees) under this paragraph (l) if the agency has failed to comply with any time limit under 5 U.S.C. 552(a)(6) and § 802.6(b)(1).

(1) If an agency has determined that unusual circumstances apply (as the term is defined in 5 U.S.C. 552(a)(6)(B)) and the agency provided a timely written notice to the requester in accordance with 5 U.S.C. 552(a)(6)(B), a failure described in 5 U.S.C. 552(a)(6)(B) is excused for an additional 10 days. If the agency fails to comply with the extended time limit, the agency may not assess any search fees (or in the case of a requester as described under this paragraph (l)(1), duplication fees).

(2) If an agency has determined that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, an agency may

charge search fees (or in the case of a requester described under paragraph (l)(1) of this section, duplication fees) if the agency has provided a timely written notice to the requester in accordance with 5 U.S.C. 552(a)(6)(B) and the agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5 U.S.C. 552(a)(6)(B)(ii).

(3) If a court has determined that exceptional circumstances exist (as that term is defined in 5 U.S.C. 552(a)(6)(C)), a failure described in 5 U.S.C. 552(a)(6)(B) shall be excused for the length of time provided by the court order.

Dated: January 18, 2017.

Nancy M. Ware,

Director.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170207156-7225-01]

RIN 0648-XF219

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Adjustment of Georges Bank and Southern New England/Mid-Atlantic Yellowtail Flounder Annual Catch Limits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; adjustment of annual catch limits.

SUMMARY: This action transfers unused quota of Georges Bank and Southern New England/Mid-Atlantic yellowtail flounder from the Atlantic scallop fishery to the Northeast multispecies fishery for the remainder of the 2016 fishing year, which ends on April 30, 2017. This quota transfer is justified when the scallop fishery is not expected to catch its entire allocations of yellowtail flounder. The quota transfer is intended to provide additional fishing opportunities for groundfish vessels to

help achieve the optimum yield for these stocks while ensuring sufficient amounts of yellowtail flounder are available for the scallop fishery.

DATES: Effective March 13, 2017, through April 30, 2017.

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Management Specialist, (978) 281-9116.

SUPPLEMENTARY INFORMATION: NMFS is required to estimate the total amount of yellowtail flounder catch from the scallop fishery on or around January 15 each year. If the scallop fishery is expected to catch less than 90 percent of its Georges Bank (GB) or Southern New England/Mid-Atlantic (SNE/MA) yellowtail flounder sub-ACL, the Regional Administrator (RA) has the authority to reduce the scallop fishery sub-annual catch limit (sub-ACL) for these stocks to the amount projected to be caught, and increase the groundfish fishery sub-ACL for these stocks up to the amount reduced from the scallop fishery. This adjustment is intended to help achieve optimum yield for these stocks, while not threatening an overage of the ACLs for the stocks by the groundfish and scallop fisheries.

Based on the most current available data, we project that the scallop fishery will have unused quota in the 2016 fishing year. The scallop fishery is projected to catch approximately 2 mt of GB yellowtail flounder, or 5 percent of its 2016 fishing year sub-ACL, and approximately 17 mt of SNE/MA yellowtail flounder, or 53 percent of its 2016 fishing year sub-ACL. Because the scallop fishery is not expected to catch its entire allocation of GB and SNE/MA yellowtail flounder, this rule reduces the scallop sub-ACL for both stocks to the upper limit projected to be caught, and increases the groundfish sub-ACLs for these stocks by the same amount, effective March 13, 2017, through April 30, 2017. This transfer is based on the upper limit of expected yellowtail flounder catch by the scallop fishery, which is expected to minimize any risk of an ACL overage by the scallop fishery while still providing additional fishing opportunities for groundfish vessels.

Table 1 summarizes the revisions to the 2016 fishing year sub-ACLs, and Table 2 shows the revised allocations for the groundfish fishery as allocated between the sectors and common pool based on final sector membership for fishing year 2016.