

the occupants 10 seconds after its deployment.

i. To comply with HIRF and lightning requirements, the inflatable restraint system is considered a critical system since its deployment could have a hazardous effect on the airplane.

j. It must be shown that the inflatable restraints will not release hazardous quantities of gas or particulate matter into the cabin.

k. The inflatable restraint system installation must be protected from the effects of fire such that no hazard to occupants will result.

l. There must be a means to verify the integrity of the inflatable restraint activation system before each flight or it must be demonstrated to reliably operate between inspection intervals.

m. A life limit must be established for appropriate system components.

n. Qualification testing of the internal firing mechanism must be performed at vibration levels appropriate for a general aviation airplane.

Issued in Kansas City, Missouri, on December 6, 2016.

Kelly Broadway,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

15 CFR Part 2004

[Docket Number USTR-2016-0016]

RIN 0350-AA10

Production or Disclosure of Records, Information and Employee Testimony in Legal Proceedings

AGENCY: Office of the United States Trade Representative.

ACTION: Final rule.

SUMMARY: This rule adds subparts A and D to part 2004 of the Office of the United States Trade Representative's (USTR) regulations. Subpart A contains definitions used throughout part 2004. Subpart D governs how USTR responds to official demands and informal requests for records, information or employee testimony in connection with legal proceedings in which neither the United States nor USTR is a party. It includes the requirements and procedures for demanding or requesting parties to submit demands or requests, and factors for USTR to consider in determining whether USTR employees will provide records, information or testimony relating to their official duties.

DATES: The final rule will become effective December 13, 2016.

FOR FURTHER INFORMATION CONTACT:

Janice Kaye, Monique Ricker or Melissa Keppel, Office of General Counsel, United States Trade Representative, Anacostia Naval Annex, Building 410/Door 123, 250 Murray Lane SW., Washington, DC 20509, *jkaye@ustr.eop.gov*; *mricker@ustr.eop.gov*; *mkeppel@ustr.eop.gov*; 202-395-3150.

SUPPLEMENTARY INFORMATION: On September 22, 2016, USTR published a proposed rule to add subparts A and D to part 2004. See 81 FR 65309. The 60-day comment period ended on November 21, 2016. USTR did not receive any comments. We have made one non-substantive change to the proposed rule. In subpart A, which contain definitions used throughout part 2004, we added a new term—"OGIS"—which means the Office of Government Information Services of the National Archives and Records Administration. OGIS, offers FOIA dispute resolution services. For convenience, the entire text of the final rule is set out below.

Regulatory Flexibility Act

USTR has considered the impact of the final rule and determined that it is not likely to have a significant economic impact on a substantial number of small business entities because it is applicable only to USTR's internal operations and legal obligations. See 5 U.S.C. 601 *et seq.*

Paperwork Reduction Act

The final rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 15 CFR Part 2004

Administrative practice and procedure, Courts, Disclosure, Exemptions, Freedom of information, Government employees, Privacy, Records, Subpoenas, Testimony.

■ For the reasons stated in the preamble, the Office of the United States Trade Representative is revising part 2004 of chapter XX of title 15 of the Code of Federal Regulations to read as follows:

PART 2004—DISCLOSURE OF RECORDS AND INFORMATION

Subpart A—Definitions

Sec.

2004.0 Definitions.

Subpart B—Freedom of Information Act Policies and Procedures [Reserved]

2004.1 through 2004.9 [Reserved]

Subpart C—Privacy Act Policies and Procedures [Reserved]

2004.10 through 2004.29 [Reserved]

Subpart D—Production or Disclosure of USTR Records, Information and Employee Testimony in Legal Proceedings

2004.30 Purpose and scope.

2004.31 Definitions.

2004.32 Production prohibited unless approved.

2004.33 Factors the General Counsel may consider.

2004.34 Submitting demands and requests.

2004.35 Processing demands and requests.

2004.36 Restrictions that apply to testimony.

2004.37 Restrictions that apply to released records or information.

2004.38 In the event of an adverse ruling.

2004.39 Fees.

Subpart A—Definitions

Authority: 19 U.S.C. 2171(e)(3).

§ 2004.0 Definitions.

For purposes of this part:

Days, unless otherwise indicated, means working days, and does not include Saturdays, Sundays, and legal public holidays. If the last day of a specified period falls on a Saturday, Sunday, or legal public holiday, the period will be extended until the next working day.

FOIA means the Freedom of Information Act, as amended, 5 U.S.C. 552.

Privacy Act means the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

OGIS means the Office of Government Information Services of the National Archives and Records Administration, which offers FOIA dispute resolution services.

USTR means the Office of the United States Trade Representative.

Subpart B—Freedom of Information Act Policies and Procedures [Reserved]

§§ 2004.1 through 2004.9 [Reserved]

Subpart C—Privacy Act Policies and Procedures [Reserved]

§§ 2004.10 through 2004.29 [Reserved]

Subpart D—Production or Disclosure of USTR Records, Information and Employee Testimony in Legal Proceedings

Authority: 5 U.S.C. 301; 19 U.S.C. 2171(e)(3).

§ 2004.30 Purpose and scope.

(a) *Why are we issuing this rule?* This subpart establishes the procedures USTR will follow when any federal, state or local government court or other

authority seeks production of USTR records or information, or testimony relating to an employee's official duties, in the context of a legal proceeding. Parties seeking records, information or testimony must comply with these requirements when submitting demands or requests to USTR.

(b) *What does this rule cover?* This subpart applies to demands or requests for records, information or testimony in legal proceedings in which USTR is not a named party. It does not apply to: Demands or requests for a USTR employee to testify as to facts or events that are unrelated to his or her official duties or to USTR's functions; FOIA or Privacy Act requests; or Congressional demands or requests for records or testimony.

(c) *Not a waiver.* (1) By providing these policies and procedures, USTR does not waive the sovereign immunity of the United States.

(2) The production of records, information or testimony pursuant to this subpart does not constitute a waiver by USTR of any privilege.

(d) This subpart provides guidance for USTR's internal operations and does not create any right or benefit, substantive or procedural, that a party may rely upon in any legal proceeding against USTR or the United States.

§ 2004.31 Definitions.

For purposes of this subpart:

Demand means a request, order, subpoena or other demand of a federal, state or local court or other authority for records, information or employee testimony in a legal proceeding in which USTR is not a named party.

Employee means any current or former employee or officer of USTR, including contractors, detailees, interns, and any individual who has served or is serving in any consulting or advisory capacity to USTR, whether formal or informal.

General Counsel means USTR's General Counsel or a person within USTR's Office of General Counsel to whom the General Counsel has delegated authority to act under this subpart.

Legal proceeding means any matter, including all phases of litigation, before a court of law, administrative board or tribunal, commission, administrative law judge, hearing officer, or other body that conducts a legal or administrative proceeding.

Records or information means all documents and materials that are USTR agency records under the FOIA; any original or copy of a record or other property, no matter what media, contained in USTR files; and any other

information or materials acquired by a USTR employee in the performance of his or her official duties or because of his or her official status.

Request means any informal request, by whatever method, in connection with a legal proceeding, seeking production of records, information or testimony that has not been ordered by a court or other competent authority.

Testimony means any written or oral statements, including depositions, answers to interrogatories, affidavits, declarations and recorded interviews made by an individual about USTR information in connection with a legal proceeding.

§ 2004.32 Production prohibited unless approved.

(a) *Approval required.* An employee or any other person or entity in possession of records or information may not produce those records or information, or provide any testimony related to the records or information, in response to any demand or request without prior written approval from the General Counsel.

(b) *Penalties.* Any person or entity that fails to comply with this subpart may be subject to the penalties provided in 18 U.S.C. 641 and other applicable laws. A current employee also may be subject to administrative or disciplinary proceedings.

§ 2004.33 Factors the General Counsel may consider.

The General Counsel may grant an employee permission to testify regarding USTR matters and to produce records and information in response to a demand or request. Among the relevant factors the General Counsel may consider in making this determination are whether:

(a) The requested records, information or testimony are reasonable in scope, relevant and material to the pending action, and unavailable from other sources such as a non-USTR employee, or a USTR employee other than the employee named.

(b) Production of the records, information or testimony might result in USTR appearing to favor one litigant over another.

(c) USTR has an interest in the decision that may be rendered in the legal proceeding.

(d) Approving the demand or request would assist or hinder USTR in performing statutory duties or unduly burden USTR resources.

(e) The demand or request is unduly burdensome or otherwise inappropriate under the rules of discovery or procedure governing the case or matter in which the demand or request arose.

(f) Production of the records, information or testimony might violate or be inconsistent with a statute, Executive Order, regulation or other legal authority.

(g) Disclosure, including release in camera, is appropriate or necessary under the relevant substantive law concerning privilege.

(h) Disclosure, except when in camera and necessary to assert a claim of privilege, would reveal information properly classified or other matters exempt from unrestricted disclosure.

(i) Disclosure would interfere with ongoing enforcement proceedings, compromise constitutional rights, reveal the identity of an intelligence source or confidential informant, or disclose trade secrets or similarly confidential commercial or financial information.

(j) Any other appropriate factor.

§ 2004.34 Submitting demands and requests.

(a) *Where do I send a demand or request?* To make a demand or request for records, information or testimony you should write directly to the General Counsel. Heightened security delays mail delivery. To avoid mail delivery delays, we strongly suggest that you email your demand or request to TOUHY@ustr.eop.gov. The mailing address is General Counsel, Office of the United States Trade Representative, Anacostia Naval Annex, Building 410/Door 123, 250 Murray Lane SW., Washington, DC 20509. To ensure delivery, you should mark the subject line of your email or your envelope and letter "Touhy Request."

(b) *When should I submit it?* You should submit your demand or request at least 45 calendar days in advance of the date on which the records, information or testimony is needed.

(c) *What must be included?* (1) A demand or request must include an affidavit or, if that is not feasible, a clear and concise statement by the party or his or her counsel summarizing the legal and factual issues in the proceeding and explaining how the records, information or testimony will contribute substantially to the resolution of one or more specifically identified issues.

(2) A demand or request for testimony also must include an estimate of the amount of time that the employee will need to devote to the process of testifying (including anticipated travel time and anticipated duration of round trip travel), plus a showing that no document or the testimony of non-USTR persons, including retained experts, could suffice in lieu of the employee's testimony.

(d) *Limits.* The General Counsel will limit any authorization for testimony to the scope of the demand, and the scope of permissible production of records and information to that set forth in the written authorization.

(e) *Failure to meet requirements and exceptions.* USTR may oppose any demand or request that does not meet the requirements set forth in this subpart. The General Counsel may grant exceptions to the requirements in this subpart upon a showing of compelling need, to promote a significant interest of USTR or the United States, or for other good cause.

§ 2004.35 Processing demands and requests.

(a) The General Counsel will review a request or demand to produce or disclose records, information or testimony and determine whether, or under what conditions, to authorize the employee to testify regarding USTR matters or produce records and information. The General Counsel will notify the requester of the final determination, the reasons for the grant or denial of the demand or request, and any conditions on disclosure.

(b) When necessary, the General Counsel will coordinate with the U.S. Department of Justice to file appropriate motions, including motions to remove the matter to Federal court, to quash, or to obtain a protective order.

(c) The General Counsel will process demands and requests in the order in which they are received. Absent unusual circumstances and depending on the scope of the demand or request, the General Counsel will respond within 45 calendar days of the date USTR receives all information necessary to evaluate the demand or request.

§ 2004.36 Restrictions that apply to testimony.

(a) The General Counsel may impose conditions or restrictions on the testimony of USTR employees including, for example, limiting the scope of testimony or requiring the requester and other parties to the legal proceeding to agree that the testimony transcript will be kept under seal or will only be used or made available in the particular legal proceeding for which testimony was requested. The General Counsel also may require a copy of the testimony transcript at the requester's expense.

(b) USTR may offer the employee's written declaration in lieu of testimony.

(c) If authorized to testify pursuant to this subpart, an employee may testify as to relevant facts within his or her personal knowledge, but, unless

specifically authorized to do so by the General Counsel, the employee must not:

(1) Disclose classified, confidential or privileged information; or

(2) For a current USTR employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or USTR's mission or functions, unless testimony is provided on behalf of the United States. A former employee can provide expert or opinion testimony where the testimony involves only general expertise gained while employed as a USTR employee.

§ 2004.37 Restrictions that apply to released records and information.

(a) The General Counsel may impose conditions or restrictions on the release of records and information, including requiring the parties to the legal proceeding to obtain a protective order or to execute a confidentiality agreement to limit access and further disclosure. The terms of a protective order or confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements already have been executed, USTR may condition the release of records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, USTR may present original records for examination in response to a demand or request, but the records cannot be marked or altered or presented as evidence or otherwise used in a manner by which they could lose their status as original records. In lieu of original records, certified copies will be presented for evidentiary purposes. (See 28 U.S.C. 1733).

§ 2004.38 In the event of an adverse ruling.

(a) Notwithstanding USTR's rejection of a demand or request for records, information or testimony, if a court or other competent authority orders a USTR employee to comply with the demand, the employee promptly must notify the General Counsel of the order, and must respectfully decline to comply, citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

(b) To seek reconsideration of USTR's rejection of a demand or request, or of any restrictions on receiving records, information or testimony, a requester must send a petition for reconsideration in accordance with § 2004.34(a) within 10 days of the date of the determination. The petition must contain a clear and concise statement of the basis for the reconsideration with supporting authorities. Determinations about

petitions for reconsideration are within the discretion of the United States Trade Representative or his/her designee, and are final.

(c) Pursuant to section 704 of the Administrative Procedure Act, 5 U.S.C. 704, a petition for reconsideration of a final determination under this section is a prerequisite to judicial review.

§ 2004.39 Fees.

(a) USTR may condition the production of records, information or an employee's appearance on advance payment of reasonable costs, which may include but are not limited to those associated with employee search time, copying, computer usage, and certifications.

(b) Witness fees will include fees, expenses and allowances prescribed by the rules applicable to the particular legal proceeding. If no fees are prescribed, USTR will base fees on the rule of the federal district court closest to the location where the witness will appear. Such fees may include but are not limited to time for preparation, travel and attendance at the legal proceeding.

Janice Kaye,

Chief Counsel for Administrative Law, Office of the U.S. Trade Representative.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 514, 515, 601, 607, and 1271

[Docket No. FDA-2005-N-0464 (Formerly Docket No. 2005N-0403)]

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs" that appeared in the **Federal Register** of August 31, 2016 (81 FR 60169). That final rule amended current regulations