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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 1

USDA Freedom of Information Act Regulations

AGENCY: Department of Agriculture.

ACTION: Final rule.

SUMMARY: The Department of Agriculture is issuing a final rule revising its regulations implementing the Freedom of Information Act (FOIA). This final rule implements the Electronic Freedom of Information Act Amendments of 1996.

EFFECTIVE DATE: August 28, 2000.

FOR FURTHER INFORMATION CONTACT: Andrea E. Fowler, FOIA Officer, Office of Communications, at (202) 720-8164.

SUPPLEMENTARY INFORMATION: On May 4, 1998 (63 FR 24467), USDA requested public comment on proposed revisions to its regulations at 7 CFR Part 1 implementing the Freedom of Information Act. This revision is necessary to implement the Electronic Freedom of Information Act Amendments of 1996, Public Law 104-231 (E-FOIA).

The proposed rule provided for the expedited processing of certain categories of requesters; proposed "multitrack" processing requirements; incorporated new processing deadlines and appeal rights; implemented the E-FOIA provisions requiring agencies to generally provide records in the form or format requested, extended agency regulations to the processing of electronic records, and provides for frequently requested records as a category of reading room records.

Analysis of Public Comments and the Final Rule

USDA received three comment letters in response to the proposed revisions to

USDA's FOIA regulations, one from a trade association representing news editors and reporters; one from a trade association representing private citizens; and one from a natural resource community group involved in natural resource issues. The commenters raised several issues regarding the proposed rule, generally seeking clarification of provisions implementing E-FOIA.

Regarding section 1.4(a)(4), one of the trade associations requested that USDA reconsider the provision which allows USDA agencies to decide on a case-by-case basis whether records that have already been subject to several requests should be placed in agency reading rooms. The commenter would like USDA to change this section to cover only records that have not been subject to subsequent FOIA requests instead of records that have been subject to several requests. The regulation tracks the language of the statute. Therefore, USDA believes that this section of the regulation as proposed is appropriate.

Regarding section 1.9(b)(2), the community group and the association of news editors and reporters requested that USDA broaden the circumstances for expedited processing of FOIA requests. USDA believes, as a matter of policy, that expanding the criteria as embodied in the proposed regulation as suggested by the commenters would be counter to even-handed treatment of the public. In essence, the commenters desire that self-selected requesters be placed in line ahead of most members of the requesting public. One specific suggestion to USDA was to include the Department of Justice regulatory provision allowing expedited treatment when a request involves the loss of substantial due process rights. In this connection, USDA points out that one of the primary missions of the Department of Justice is the administration of criminal justice. USDA does not share the administration of criminal justice as one of its primary missions, and believes that the addition of loss of substantial due process rights as a ground for expedited processing is not necessary.

Regarding section 1.9(2)(c) the association of news editors and reporters requested that USDA incorporate a provision similar to that adopted by the Department of Justice and the Federal Deposit Insurance

Corporation in their FOIA regulations with regard to the formality of certifications needed to obtain expedited treatment. More specifically, and consistently with E-FOIA, the USDA proposed rule provided that a requester is entitled to expedited treatment only where failure to obtain the records expeditiously could pose an imminent threat to the life or physical safety of a person, or where the requester is a person primarily engaged in disseminating information and there is an urgency to inform the public concerning actual or alleged agency activity. A requester seeking expedited processing must submit a certified statement describing the basis for requesting expedited treatment. The Department of Justice and Federal Deposit Insurance Corporation regulations, however, provide that the formality of certification may be waived as a matter of administrative discretion. The association of news editors and reporters requests that USDA incorporate a similar waiver provision. The certification required by USDA is straightforward and, therefore, we do not expect that it will be burdensome for eligible requesters to submit a certification with their initial requests.

The association of news editors and reporters requested that USDA incorporate language that the denial of a request for expedited processing should be appealable. This language is already included in proposed section 1.9 of the regulations.

Regarding section 1.5, the community group requested that USDA remove the requirement that all requests for records shall be deemed to have been made pursuant to FOIA by changing the word "shall" to "should"; and change the requirement that when a requester wants documents relating to pending litigation that the requester identify the court and its location. We believe that considering all requests for records under FOIA will confer more rights on the requester, and therefore we will keep the word "shall" in the language. Also, we believe that identifying the court and its location is part of the requirement to reasonably describe the documents requested.

Regarding section 1.6, the community group requested that USDA remove this section which pertains to aggregating requests, asserting that it violates the due process clause of the constitution.

We do not concur because aggregation of requests is specifically permitted by 5 U.S.C. 552(a)(6)(B)(iv).

Regarding section 1.8, the community group requested that USDA provide a better description of multitrack processing and give examples. USDA does not have a centralized FOIA process in which requests will be processed in a central multitracking process. Each agency within USDA which decides to have a multitracking processing system will provide a description of its system and how it works in its respective agency regulations and directives.

Regarding section 1.19, the community group requested that USDA better describe the term "promptly available" as it relates to making records available to any person submitting a FOIA request. The group also wants us to incorporate Attorney General Reno's October 4, 1993, memo on discretionary releases into the regulation. We believe that the term "promptly available" clearly indicates that FOIA requests should be processed as soon as reasonably possible, considering the nature of the request, and all the facts and circumstances, including the volume and location of responsive records. We also believe that this section of the USDA regulation reflects the essence of Attorney General Reno's memo to make discretionary releases under FOIA. However, we emphasize that this does not reflect a statement of policy that USDA has specifically incorporated the Attorney General's memorandum of October 4, 1993. USDA is mindful of its obligation under the memorandum, but also is aware that the memorandum, by its terms, specifically disclaims that it extends enforceable procedural rights to requesters.

The community group requested that USDA provide a process for citizens to file a complaint about officials who intentionally violate FOIA. We believe that section 1.14 of the USDA regulations already provides a process for citizens to complain if they believe officials have intentionally violated FOIA. This section allows citizens to appeal a denial of a request for records or denial of a fee waiver to a different level of the agency. Citizens also have the right to judicial review of final appeal denials.

The community group requested that USDA provide for FOIA requests via electronic mail over the Internet. USDA believes that this decision is more appropriately left to its individual program agencies and staff offices. This is so because of decentralization of FOIA processing within USDA and the varying electronic capabilities of the

numerous agencies and offices that would be affected.

Finally, upon review, USDA is modifying the language of Section 1.8(c) to accommodate situations where an agency might have several processing tracks, so that the requester will have the opportunity to modify the request to qualify for a faster track rather than the "fastest" track, as in the proposed regulation. This approach is more logical than simply providing for modification to qualify for the "fastest track," where there may be several tracks to which the request might be assigned.

Executive Order 12866

Because this rule has been determined to be not significant, the Office of Management and Budget (OMB) did not review it under Executive Order 12866. This rule will not have any economic impact. Under these circumstances, the Secretary has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified must be exhausted prior to any judicial challenge of the application of the provisions of this rule.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

USDA certifies that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it will not have a significant economic impact on a substantial number of small entities. This rule implements the Freedom of Information Act (5 U.S.C. 552), a statute concerning the release of Federal Government records, and does not economically impact Federal Government relations with the private sector.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

USDA certifies that this rule does not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 7 CFR Part 1

Administrative practice and procedure, Freedom of Information, Privacy.

Accordingly, 7 CFR, part 1, is amended as follows:

1. The authority citation for 7 CFR, part 1, continues to read as follows:

Authority: 5 U.S.C. 301, unless otherwise noted.

2. Part 1 is amended in subpart A by revising §§ 1.1 through 1.20 and §§ 1.22 through 1.23 and by adding §§ 1.21, 1.24 and 1.25 to read as follows:

PART 1—ADMINISTRATIVE REGULATIONS

Subpart A—Official Records

- Sec.
- 1.1 Purpose and scope.
 - 1.2 Policy.
 - 1.3 Agency implementing regulations.
 - 1.4 Public access to certain materials.
 - 1.5 Requests for records.
 - 1.6 Aggregating requests.
 - 1.7 Agency response to requests for records.
 - 1.8 Multitrack processing.
 - 1.9 Expedited processing.
 - 1.10 Search services.
 - 1.11 Review services.
 - 1.12 Handling information from a private business.
 - 1.13 Date of receipt of requests or appeals.
 - 1.14 Appeals.
 - 1.15 General provisions respecting release of records.
 - 1.16 Extension of administrative deadlines.
 - 1.17 Failure to meet administrative deadlines.
 - 1.18 Fee schedule.
 - 1.19 Exemptions and discretionary release.
 - 1.20 Annual report.
 - 1.21 Compilation of new records.
 - 1.22 Authentication.
 - 1.23 Records in formal adjudication proceedings.
 - 1.24 Preservation of records.
 - 1.25 Implementing regulations for the Office of the Secretary and the Office of Communications.
- Appendix A—Fee Schedule

Subpart A—Official Records

Authority: 5 U.S.C. 301, 552; 7 U.S.C. 3125a; 31 U.S.C. 9701; and 7 CFR 2.28(b)(7)(viii).

§ 1.1 Purpose and scope.

This subpart establishes policy, procedures, requirements, and responsibilities for administration and coordination of the Freedom of Information Act ("FOIA"), 5 U.S.C. 552, pursuant to which any person may obtain official records. It also provides rules pertaining to the disclosure of records pursuant to compulsory process. This subpart also serves as the implementing regulations (referred to in § 1.3, "Agency implementing regulations") for the Office of the Secretary (the immediate offices of the Secretary, Deputy Secretary, Under Secretaries and Assistant Secretaries) and for the Office of Communications. The Office of Communications has the

primary responsibility for implementation of the FOIA in the Department of Agriculture ("USDA" or "Department"). The term "agency" or "agencies" is used throughout this subpart to include both USDA program agencies and staff offices.

§ 1.2 Policy.

(a) Agencies of USDA shall comply with the time limits set forth in the FOIA and in this subpart for responding to and processing requests and appeals for agency records, unless there are unusual circumstances within the meaning of 5 U.S.C. 552(a)(6)(B) and § 1.16(b). An agency shall notify a requester in writing whenever it is unable to respond to or process a request or appeal within the time limits established by the FOIA.

(b) All agencies of the Department shall comply with the fee schedule provided as appendix A to this subpart, with regard to the charging of fees for providing copies of records and related services to requesters.

§ 1.3 Agency implementing regulations.

Each agency of the Department shall promulgate regulations setting forth the following:

(a) The location and hours of operation of the agency office or offices where members of the public may gain access to those materials required by 5 U.S.C. 552(a)(2) and § 1.4 to be made available for public inspection and copying.

(b) Information regarding the publication and distribution (by sale or otherwise) of indexes and supplements to indexes that are maintained in accordance with the requirements of 5 U.S.C. 552(a)(2) and § 1.4(c);

(c) The title and mailing address of the official or officials of the agency authorized to receive requests for records submitted in accordance with § 1.5(a), and to make determinations regarding whether to grant or deny such requests. Authority to make such determinations includes authority to:

(1) Extend the 20 working day administrative deadline for reply pursuant to § 1.16;

(2) Make discretionary releases pursuant to § 1.19(b);

(3) Make determinations regarding the charging of fees pursuant to appendix A to this subpart;

(d) The title and mailing address of the agency official who is authorized to receive appeals submitted in accordance with § 1.14 and to make determinations regarding whether to grant or deny such appeals. Authority to determine appeals includes authority to:

(1) Extend the 20 working day administrative deadline for reply

pursuant to § 1.16 (to the extent the maximum extension authorized by § 1.16(c) was not used with regard to the initial request;

(2) Make discretionary releases pursuant to § 1.19(b);

(3) Make determinations regarding the charging of fees pursuant to appendix A to this subpart; and

(e) Other information which would be of concern to a person wishing to request records from that agency in accordance with this subpart.

§ 1.4 Public access to certain materials.

(a) In accordance with 5 U.S.C. 552(a)(2), each agency within the Department shall make the following materials available for public inspection and copying (unless they are promptly published and copies offered for sale):

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

(2) Those statements of policy and interpretation which have been adopted by the agency and are not published in the **Federal Register**;

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

(4) Copies of all records, regardless of form or format, which have been released pursuant to a FOIA request under 5 U.S.C. 552(a)(3), and which because of the nature of their subject matter, have become or are likely to become the subject of subsequent requests for substantially the same records. Agencies shall decide on a case by case basis whether records fall into this category, based on the following factors:

(i) Previous experience with similar records;

(ii) The particular characteristics of the records involved, including their nature and the type of information contained in them; and

(iii) The identity and number of requesters and whether there is widespread media, historical, academic, or commercial interest in the records.

(5) A general index of the records referred to in paragraph (a)(4) of this section.

(b) Records encompassed within paragraphs (a)(1) through (a)(5) of this section created on or after November 1, 1996, shall be made available to the public by computer telecommunications or, if computer telecommunications means have not been established by the agency, by other electronic means.

(c) Each agency of the Department shall maintain and make available for public inspection and copying current indexes providing identifying

information regarding any matter issued, adopted or promulgated after July 4, 1967, and required by paragraph (a) of this section to be made available or published. Each agency shall publish and make available for distribution copies of such indexes and supplements to such indexes at least quarterly, unless it determines by notice published in the **Federal Register** that publication would be unnecessary and impracticable. After issuance of such notice, each agency shall provide copies of any index upon request at a cost not to exceed the direct cost of duplication.

(d) Each agency is responsible for preparing reference material or a guide for requesting records or information from that agency. This guide shall also include an index of all major information systems, and a description of major information and record locator systems.

(e) Each agency shall also prepare a handbook for obtaining information from that agency. The handbook should be a short, simple explanation to the public of what the FOIA is designed to do, and how a member of the public can use it to access government records. The handbook should be available on paper and through electronic means, and it should identify how a requester can access agency Freedom of Information Act annual reports. Similarly, the annual reports should refer to the handbook and how to obtain it.

(f) It is appropriate to make frequently requested records available in accordance with paragraph (a)(4) of this section in situations where public access in a timely manner is important, and it is not intended to apply where there may be a limited number of requests over a short period of time from a few requesters. Agencies may remove a record from this access medium when the appropriate official determines that it is unlikely there will be substantial further requests for that document.

§ 1.5 Requests for records.

(a) Any person who wishes to inspect or obtain copies of any record of any agency of the Department shall submit a request in writing and address the request to the official designated in regulations promulgated by that agency. The requester may ask for a fee waiver. All such requests for records shall be deemed to have been made pursuant to the Freedom of Information Act, regardless of whether the request specifically mentions the Freedom of Information Act. To facilitate processing of a request, the requester should place the phrase "FOIA REQUEST" in capital letters on the front of the envelope or on

the cover sheet of the facsimile transmittal.

(b) A request must reasonably describe the records to enable agency personnel to locate them with reasonable effort. Where possible, a requester should supply specific information regarding dates, titles, names of individuals, names of offices, and names of agencies or other organizations that may help identify the records. If the request relates to a matter in pending litigation, the requester should identify the court and its location.

(c) If an agency determines that a request does not reasonably describe the records, the agency shall inform the requester of this fact and extend the requester an opportunity to clarify the request or to confer promptly with knowledgeable agency personnel to attempt to identify the records the requester is seeking. The "date of receipt" in such instances, for purposes of § 1.13, shall be the date of receipt of the amended or clarified request.

(d) If a request for records or a fee waiver made under this subpart is denied, the requester shall have the right to appeal the denial. Requesters also may appeal agency determinations of a requester's status for purposes of fee levels under sec. 5 of appendix A to this subpart. All appeals must be in writing and addressed to the official designated in regulations promulgated by the agency which denied the request. To facilitate processing of an appeal, the requester should place the phrase "FOIA APPEAL" in capital letters on the front of the envelope or on the cover sheet of the fax transmittal.

(e) Requests that are not addressed to a specific agency in USDA, or which pertain to more than one USDA agency, or which are sent to the wrong agency of USDA, should be forwarded to the Department's FOIA Officer in the Office of Communications, U.S. Department of Agriculture, Washington, DC 20250.

(f) The Department FOIA Officer will determine which agency or agencies should process the request, and, where necessary, refer the request to the appropriate agency or agencies. The Department FOIA Officer will also notify the requester of the referral and of the name of each agency to which the request has been referred.

(g) A request will be properly received when it is in the possession of the component agency that has responsibility for maintaining the requested records.

(h) Each agency shall develop and maintain a record of all written requests and appeals received in that agency. The record shall include the names of

the requester; a brief summary of the information requested; whether the request or appeal was granted, denied, or partially denied; the exemption from mandatory disclosure under 5 U.S.C. 552(b) upon which any denial was based; and the amount of any fees associated with the request or appeal.

§ 1.6 Aggregating requests.

When an agency reasonably believes that a requester, or a group of requesters acting in concert, is attempting to break a request down into a series of requests for the purpose of evading the assessment of fees, the agency may aggregate any such requests and charge accordingly. One element that may be considered in determining whether such a belief would be reasonable is the brevity of the time period during which the requests have been made.

§ 1.7 Agency response to requests for records.

(a) 5 U.S.C. 552(a)(6)(A)(i) provides that each agency of the Department to which a request for records is submitted in accordance with § 1.5(a) shall inform the requester of its determination concerning that request within 20 working days of its date of receipt (excepting Saturdays, Sundays, and legal public holidays), plus any extension authorized under § 1.16. If the agency determines to grant the request, it shall inform the requester of any conditions surrounding the granting of the request (*e.g.*, payment of fees) and the approximate date upon which the agency will provide the requested records. If the agency grants only a portion of the request, it shall treat the portion not granted as a denial, and make a reasonable effort to estimate the volume of the records denied and provide this estimate to the requester, unless providing such an estimate would harm an interest protected by an exemption of the FOIA. If the agency determines to deny the request in part or in whole, it shall immediately inform the requester of that decision and provide the following:

- (1) The reasons for the denial;
- (2) The name and title or position of each person responsible for denial of the request;
- (3) The requester's right to appeal such denial and the title and address of the official to whom such appeal is to be addressed; and
- (4) The requirement that such appeal be made within 45 days of the date of the denial.

(b) If the reason for not fulfilling a request is that the records requested are in the custody of another agency outside USDA, other than in the permanent

custody of the National Archives and Records Administration ("NARA"), the agency shall inform the requester of this fact and shall forward the request to that agency or Department for processing in accordance with its regulations. If the records are in the permanent custody of NARA, the agency shall so inform the requester. Information about obtaining access to records at NARA may be obtained through the NARA Archival Information Locator (NAIL) Database at <http://www.nara.gov/nara.nail.html>, or by calling NARA at (301) 713-6800. If the agency has no knowledge of requested records or if no records exist, the agency shall notify the requester of that fact.

§ 1.8 Multitrack processing.

(a) When an agency has a significant number of requests, the nature of which precludes a determination within 20 working days, the requests may be processed in a multitrack processing system, based on the date of receipt, the amount of work and time involved in processing the request, and whether the request qualifies for expedited processing.

(b) Agencies may establish as many processing tracks as appropriate; processing within each track shall be based on a first-in, first-out concept, and rank-ordered by the date of receipt of the request.

(c) Agencies may provide a requester whose request does not qualify for the fastest track an opportunity to limit the scope of the request in order to qualify for a faster track. This multitrack processing system does not lessen agency responsibility to exercise due diligence in processing requests in the most expeditious manner possible.

(d) Agencies shall process requests in each track on a "first-in, first-out" basis, unless there are unusual circumstances as set forth in § 1.16, or the requester is entitled to expedited processing as set forth in § 1.9.

§ 1.9 Expedited processing.

(a) A requester may apply for expedited processing at the time of the initial request for records. Within ten calendar days of its receipt of a request for expedited processing, an agency shall decide whether to grant it, and shall notify the requester of the decision. Once the determination has been made to grant expedited processing, an agency shall process the request as soon as practicable. If a request for expedited processing is denied, the agency shall act expeditiously on any appeal of that decision.

(b) A request or appeal will be taken out of order and given expedited treatment whenever the agency determines that the requester has established either of the following criteria:

(1) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) An urgency to inform the public about an actual or alleged federal government activity, if made by an individual primarily engaged in disseminating information. Representatives of the news media would normally qualify as individuals primarily engaged in disseminating information; however, other requesters must demonstrate that their primary activity involves publishing or otherwise disseminating information to the public as a whole, and not just a particular segment or group. "Urgency" contemplates that the information has a particular value that will be lost if not disseminated quickly. Ordinarily this means a breaking news story of general public interest. Information of historical interest only or information sought for litigation or commercial activities would not meet the test of urgency, nor would a news media publication or broadcast deadline unrelated to the news breaking nature of the information.

(c) A requester who seeks expedited processing must provide a written statement that the requester has certified to be true and correct to the best of the requester's knowledge, explaining in detail the basis for requesting expedited processing. The agency will not consider the request to have been received unless accompanied by a written, certified statement, and will be under no obligation to consider the request for expedited processing until it receives such a written, certified statement.

(d) the same procedures apply to requests for expedited processing of administrative appeals.

§ 1.10 Search services.

Search services are services of agency personnel—clerical or professional—used in trying to find the records, that are responsive to a request. Search services includes both manual and electronic searches and time spent examining records for the purpose of finding information that is within the scope of the request. Search services also include services to transport personnel to places of record storage, or records to the location of personnel for

the purpose of the search, if such services are reasonably necessary.

§ 1.11 Review services.

(a) Review services are services of agency personnel—clerical or professional—in examining records, both paper and electronic, located in response to a request that is for a commercial use (as specified in sec. 6 of appendix A to this subpart) to determine whether any portion of any record located is exempt from mandatory disclosure.

(b) Review services include processing any records for disclosure *e.g.*, doing all that is necessary to redact exempt portions and otherwise prepare records for release.

(c) Review services do not include the time spent resolving general legal or policy issues regarding the application of exemptions.

§ 1.12 Handling information from a private business.

Each USDA agency is responsible for making the final determination with regard to the disclosure or nondisclosure of information in agency records that has been submitted by a business. When, in the course of responding to an FOIA request, an agency cannot readily determine whether the information obtained from a person is privileged or confidential business information, the policy of USDA is to obtain and consider the views of the submitter of the information and to provide the submitter an opportunity to object to any decision to disclose the information. If a request (including a subpoena duces tecum as described in § 1.215) is received in USDA for information that has been submitted by a business, the agency shall:

(a) Provide the business information submitter with prompt notification of a request for that information (unless it is readily determined by the agency that the information requested should not be disclosed or, on the other hand, that the information is not exempt by law from disclosure). Afford business information submitter reasonable time in which to object to the disclosure of any specified portion of the information. The submitter must explain fully all grounds upon which disclosure is opposed. For example, if the submitter maintains that disclosure is likely to cause substantial harm to its competitive position, the submitter must explain item-by-item why disclosure would cause such harm. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under FOIA;

(b) Notify the requester of the need to inform the submitter of a request for submitted business information;

(c) Determine whether the requested records are exempt from disclosure or must be released;

(d) Provide business information submitters with notice of any determination to disclose such records prior to the disclosure date, in order that the matter may be considered for possible judicial intervention; and

(e) Notify business information submitters promptly of all instances in which FOIA requesters bring suit seeking to compel disclosure of submitted information.

§ 1.13 Date of receipt of requests or appeals.

The date of receipt of a request or appeal shall be the date it is received in the agency and office responsible for the administrative processing of FOIA requests or appeals.

§ 1.14 Appeals.

(a) Requesters seeking administrative appeal of a denial of a request for records or denial of a fee waiver must ensure that the appeal is received by the agency within 45 days of the date of the denial letter.

(b) Each agency shall provide for review of appeals by an official different from the official or officials designated to make initial denials.

(c) 5 U.S.C. 552(a)(6)(A)(ii) provides that each agency in the Department to which an appeal of a denial is submitted shall inform the requester of its determination concerning that appeal within 20 working days (excepting Saturdays, Sundays, and legal public holidays), plus any extension authorized by § 1.16, of its date of receipt. If the agency determines to grant the appeal, it shall inform the requester of any conditions surrounding the granting of the request (*e.g.*, payment of fees) and the approximate date upon which compliance will be effected. If the agency grants only a portion of the appeal, it shall treat the portion not granted as a denial. If it determines to deny the appeal either in part or in whole, it shall inform the requester of that decision and of the following:

(1) The reasons for denial;

(2) The name and title or position of each person responsible for denial of the appeal; and

(3) The right to judicial review of the denial in accordance with 5 U.S.C. 552(a)(4).

(d) Each agency, upon a determination that it wishes to deny an appeal, shall send a copy of the records

requested and of all correspondence relating to the request to the Assistant General Counsel, General Law Division, Office of the General Counsel ("Assistant General Counsel"). When the volume of records is so large as to make sending a copy impracticable, the agency shall enclose an informative summary of those records. The agency shall not deny an appeal until it receives concurrence from the Assistant General Counsel.

(e) The Assistant General Counsel shall promptly review the matter (including necessary coordination with the agency) and render all necessary assistance to enable the agency to respond to the appeal within the administrative deadline or any extension of the administrative deadline.

§ 1.15 General provisions respecting release of records.

(a) When releasing documents, agencies shall provide the record in any form or format the requester specifies, if the record is readily reproducible in that form or format. Agencies shall make reasonable efforts to maintain their records in forms or formats that are reproducible. In responding to requests for records, agencies shall make reasonable efforts to search for records in electronic form or format, except when such efforts would significantly interfere with the operation of an agency's automated information system. Such determinations shall be made on a case-by-case basis.

(b) In the event a requested record contains some portions that are exempt from mandatory disclosure and others that are not, the official responding to the request shall ensure that all reasonably segregable nonexempt portions are disclosed, and that all exempt portions are identified according to the specific exemption or exemptions which are applicable. The amount of deleted information shall be indicated on the released portion of paper records. Deletions may be marked by use of brackets or darkened areas indicating removal of information, or by any other method that would reasonably demonstrate the extent of the deletion. In the case of electronic deletion, or deletion in audiovisual or microfiche records, if technically feasible, the amount of redacted information shall be indicated at the place in the records, if technically feasible, the amount of redacted information shall be indicated at the place in the record where such deletion was made. This may be done by use of brackets, shaded areas, or some other identifiable technique which

will clearly show the limits of the deleted information.

(c) If, in connection with a request or an appeal, a charge is to be made in accordance with sec. 8 of appendix A to this subpart, agencies shall inform the requester of the fee amount and of the basis for the charge. Each agency, in accordance with sec. 8 of appendix A to this subpart, may require payment of the entire fee, or a portion of the fee, before it provides the requested records. An agency shall require full payment of any delinquent fee owed by the requester plus any applicable interest prior to releasing records on a subsequent request or appeal. If a requester refuses to remit payment in advance, an agency may refuse to process the request or appeal with written notice to that effect forwarded to the requester. The "date of receipt" appeal for which advance payment has been required shall be the date that payment is received.

(d) In the event compliance with the request or appeal involves inspection of records by the requester rather than providing copies of the records, the agency response shall include the name, mailing address, and telephone number of the person to be contacted to arrange a mutually convenient time for such inspection.

(e) Whenever duplication fees, or search fees for unsuccessful searches (see sec. 4(f) of appendix A to this subpart), are anticipated to exceed \$25.00, and the requester has not indicated, in advance, a willingness to pay fees as high as those anticipated, agencies shall notify the requester of the amount of the anticipated fee. If an extensive and therefore costly successful search is anticipated, agencies also should notify requesters of the anticipated fees. The notification shall offer the requester the opportunity to confer with agency personnel to reform the request to meet the requester's needs at a lower fee. In appropriate cases, an advance deposit in accordance with sec. 8 of appendix A to this subpart may be required.

§ 1.16 Extension of administrative deadlines.

(a) In unusual circumstances as specified in this section, when additional time is needed to respond to the initial request or to an appeal, agencies shall acknowledge the request or the appeal in writing within the 20 working day time period, describe the unusual circumstances requiring the delay, and indicate the anticipated date for a substantive response that may not exceed 10 additional working days, except as provided in the following:

(1) In instances in which the agency, with respect to a particular request, has extended the response date by 10 additional working days, if the agency finds that it cannot make a response determination within the additional 10 working day period, the agency shall notify the requester and provide the requester an opportunity to limit the scope of the request to allow the agency to process the request within the extended time limit, or an alternative time frame for processing the request or a modified request.

(2) If the requester refuses to reasonably modify the request or arrange for an alternative time frame for processing the request, the FOIA provides that such refusal shall be considered as a factor in determining whether there are exceptional circumstances that warrant granting additional time for the agency to complete its review of the records, as set forth in 5 U.S.C. 552(a)(6)(C)(iii). The term "exceptional circumstances" does not include a delay that results from a predictable agency backlog, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

(b) As used in this section, "unusual circumstances" that may justify delay are:

(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 Department or agency having a substantial interest in the determination of the request or among two or more components of agency having substantial subject-matter interest in the request.

Note to paragraph (b): Consultation regarding policy or legal issues between an agency and the Office of the General Counsel, Office of Communications, or the Department of Justice is not a basis for extension under this section.

(c) The 10-day extension authorized by this section may be divided between the initial and appellate reviews, but in no event shall the total extension exceed 10 working days.

(d) Nothing in this section shall preclude the agency and the requester from agreeing to an extension of time. Any such agreement should be confirmed in writing and should specify clearly the total time agreed upon.

§ 1.17 Failure to meet administrative deadlines.

In the event an agency fails to meet the administrative deadlines set forth in §§ 1.7 or 1.14, plus any extension authorized by § 1.16, it shall notify the requester, state the reasons for the delay, and the date by which it expects to dispatch a determination. Although the requester may be deemed to have exhausted his or her administrative remedies under 5 U.S.C. 552(a)(6)(C), the agency shall continue processing the request as expeditiously as possible and dispatch the determination when it is reached in the same manner and form as if it had been reached within the applicable deadline.

§ 1.18 Fee schedule.

Pursuant to § 2.28 of this title, the Chief Financial Officer is delegated authority to promulgate regulations providing for a uniform fee schedule applicable to all agencies of the Department regarding requests for records under this subpart. The regulations providing for a uniform fee schedule are found in appendix A to this subpart.

§ 1.19 Exemptions and discretionary release.

(a) All agency records, except those specifically exempted from mandatory disclosure by one or more provisions of 5 U.S.C. 552(b), shall be made promptly available to any person submitting a request under this subpart.

(b) Agencies are authorized, in their sole discretion, to make discretionary releases when such release is not otherwise specifically prohibited by Executive Order, statute, or regulation.

§ 1.20 Annual report.

(a) Each agency of the Department shall compile the following Freedom of Information Act statistics on a fiscal year basis beginning October 1, 1997, and report the following information to the Office of Communications no later than November 30 following the fiscal year's close:

(1) The number of requests for records received and the number of requests which were processed;

(2) The number of determinations made not to comply with initial requests for records made to it under § 1.5(a), and the reasons for each such determinations;

(3) The number of appeals made by persons under § 1.14(b), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information.

(4) A complete list of all statutes that the agency relies upon to authorize the

agency to withhold information under 5 U.S.C. 552(b)(3), a description of whether a court has upheld the decision of the agency to withhold information under each such statute, and a concise description of the scope of any information withheld;

(5) The number of requests for records pending before the agency as of September 30 of the preceding year, and the median number of days that such requests had been pending before the agency as of that date;

(6) The median number of days taken by the agency to process different types of requests;

(7) The total amount of fees collected by the agency for processing requests;

(8) The number of full-time staff of the agency devoted to processing requests for records under this section, and the total amount expended by the agency for processing such requests.

(b) Each agency shall compile the information required by paragraph (a) of this section for the preceding fiscal year into a report and submit this report to the Director of Communications, Office of Communications, no later than November 30 following the fiscal year's close.

(c) The Director of Communications, Office of Communications, shall combine the reports from all the agencies within USDA into a Departmental report, and shall submit to the Attorney General on or before February 1 of each year in accordance with 5 U.S.C. 552(e).

(d) Each agency shall make the report available to the public including by computer telecommunications, or if computer telecommunications means have not been established by the agency, by other electronic means.

§ 1.21 Compilation of new records.

Nothing in 5 U.S.C. 552 or this subpart requires that any agency create a new record in order to fulfill a request for records. However, an agency is required to provide a record in a form or format specified by a requester, if the record is readily reproducible by the agency in the form or format requested. Creation of records may be undertaken voluntarily if the agency determines this action to be in the public interest or the interest of USDA.

§ 1.22 Authentication.

When a request is received for an authenticated copy of a document which the agency determines to make available to the requesting party, the agency shall cause a correct copy to be prepared and sent to the Office of the General Counsel which shall certify the same and cause the seal of the

Department to be affixed, except that the Hearing Clerk in the Office of Administrative Law Judges may authenticate copies of documents in the records of the Hearing Clerk and that the Director of the National Appeals Division may authenticate copies of documents in the records of the National Appeals Division.

§ 1.23 Records in formal adjudication proceedings.

Records in formal adjudication proceedings are on file in the Hearing Clerk's office, Office of Administrative Law Judges, U.S. Department of Agriculture, Washington, DC 20250, and shall be made available to the public.

§ 1.24 Preservation of records.

Agencies shall preserve all correspondence relating to the requests it receives under this subpart, and all records processed pursuant to such requests, until such time as the destruction of such correspondence and records is authorized pursuant to Title 44 of the United States Code, and appropriate records disposition authority granted by NARA. Under no circumstances shall records be sent to a Federal Records Center, transferred to the permanent custody of NARA, or destroyed while they are the subject of a pending request, appeal, or civil action under the FOIA.

§ 1.25 Implementing regulations for the Office of the Secretary and the Office of Communications.

(a) For the Office of the Secretary and for the Office of Communications, the regulations required by § 1.3 are as follows:

(1) Records available for public inspection and copying may be obtained in Room 536-A, Jamie L. Whitten Federal Building, USDA, Washington, DC 20250 during the hours of 9 a.m. to 5 p.m. by prior appointment;

(2) Any indexes and supplements which are maintained in accordance with the requirements of 5 U.S.C. 552(a)(2) and § 1.5(b) will also be available in Room 536-A, Jamie L. Whitten Federal Building, USDA, Washington, DC 20250 during the hours of 9 a.m. to 5 p.m.;

(3) The person authorized to receive Freedom of Information Act requests and to determine whether to grant or deny such requests is the FOIA Officer, Office of Communications, USDA, Washington, DC 20250;

(4) The official authorized to receive appeals from denial of FOIA requests and to determine whether to grant or deny such appeals is the Director of Communications, Office of

Communications, USDA, Washington, DC 20250.

(b) The organization and functions of the Office of the Secretary and the Office of Communications is as follows:

(1) The Office of the Secretary provides the overall policy guidance and direction of the activities of the Department of Agriculture. Department-wide policy statements and announcements are made from this office.

(2) The Office of the Secretary consists of the Secretary, Deputy Secretary, Under Secretaries, Assistant Secretaries, and other staff members.

(3) In the absence of the Secretary and the Deputy Secretary, responsibility for the operation of the Department of Agriculture is as delegated at part 2, subpart A, of this title.

(4) The Office of Communications provides policy direction, review, and coordination of public information programs of the Department of Agriculture. The Office of Communications has responsibility for maintaining the flow of information to the mass communications media, various constituency groups, and the general public.

(5) The Office of Communications is headed by the Director of Communications. In the Director's absence, the Office of Communications is headed by the Deputy Director.

Appendix A to Subpart A—Fee Schedule

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Dated: July 18, 2000.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 00-18767 Filed 7-27-00; 8:45 am]

BILLING CODE 3410-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 99C-1455]

Listing of Color Additives for Coloring Sutures; D&C Violet No. 2

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of

glycolide for general surgery. The agency is also revising the nomenclature “polyglactin 910 (glycolic-lactic acid polyester)” to the generic nomenclature “copolymers of 90 percent glycolide and 10 percent L-lactide.” This action responds to a petition filed by Genzyme Surgical Products Corp.

DATES: This rule is effective August 29, 2000; except as to any provisions that may be stayed by the filing of proper objections. Submit written objections and requests for a hearing by August 28, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of June 3, 1999 (64 FR 29871), FDA announced that a color additive petition (CAP 9C0266) had been filed by Genzyme Surgical Products Corp., 600 Airport Rd., Fall River, MA 02720. The petition proposed to amend the color additive regulations in § 74.3602 *D&C Violet No. 2* (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 as a color additive in absorbable sutures prepared from homopolymers of glycolide for general surgery. The petition also proposed that the nomenclature “polyglactin 910 (glycolic-lactic acid polyester)” be revised to the generic nomenclature “copolymers of 90 percent glycolide and 10 percent L-lactide.” The petition was filed under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(d)(1)).

II. Regulatory History

The regulatory history of D&C Violet No. 2 was summarized in a final rule published in the **Federal Register** of May 7, 1990 (55 FR 18865). Since the publication of the May 7, 1990, final rule, other uses of D&C Violet No. 2 have been approved by the agency. For example, in a final rule published in the **Federal Register** of June 18, 1999 (64 FR 32803), FDA amended § 74.3602 to list D&C Violet No. 2 as a color additive in absorbable meniscal tacks made from poly(L-lactic acid).

III. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Public Law 94-295), Congress mandated the listing of color additives for use in medical devices when the color additive in the device comes into direct contact with the body for a significant period of time (section 721(a) of the act). D&C Violet No. 2 is added to absorbable sutures prepared from homopolymers of glycolide in such a way that at least some of the color additive will come into contact with the body when the sutures are in place. In addition, the sutures are intended to be absorbed by the body, and during the absorption, the color additive will be deposited in body tissue. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the petitioned use of the color additive is subject to the statutory listing requirement.

IV. The Color Additive

D&C Violet No. 2 is principally 1-hydroxy-4-[(4-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 81-48-1). It is manufactured by either condensation of quinizarin with *p*-toluidine or by condensation of 1-hydroxy-halogenoanthroquinone with *p*-toluidine. Because no chemical reaction consumes all the starting materials and yields only the desired product, both the resulting reaction mixture and commercial product will contain residual amounts of the starting materials, including *p*-toluidine. This fact is significant because Weisburger et al. have demonstrated that *p*-toluidine is a carcinogen in the mouse (Ref. 1). Residual amounts of reactants, such as *p*-toluidine, and manufacturing aids are commonly found as impurities in chemical products, including color additives.

V. Determination of Safety

Under the general safety standard of the act (section 721(b)(4)) for color additives, a color additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations (21 CFR 70.3(i)) define “safe” as “reasonable certainty that no harm will result from the intended use of the color additive.”

The color additives anticancer, or Delaney, clause of the color additive amendments (section 721(b)(5)(B) of the act) provides that no noningested color additive shall be deemed safe and shall be listed if, after tests that are appropriate for evaluating the safety of