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RECORDS SECTION

November 1, 1999

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OFFICE OF THE SECRETARIAT

Jean A. Webb, Secretary
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st St. NW
Washington, DC 20581

COMMENT

**BY FIRST CLASS MAIL
RETURN RECEIPT REQUESTED
Z 153 856 983**

Dear Ms. Webb:

Federal Register release number 99-035 and Federal Register release number 99-036 ("the releases"), which the Commodity Futures Trading Commission ("CFTC") published in the Federal Register on September 30, 1999, provide for comments to be submitted in response to the releases. For purposes of commenting on the releases, I submit this letter in my official capacity as the President of American Federation of Government Employees Local 3477 ("the union"). The union is the exclusive representative of all employees in the bargaining unit consisting of non-professional employees working in CFTC's Eastern Regional Office in New York City. A copy of the releases, which were printed from the CFTC's INTRANET, are enclosed for reference.

COMMENT 1: REQUEST FOR EXTENSION OF TIME TO COMMENT

I have read the releases. I have also made an effort to read the Privacy Act itself, in order to identify the exact language in the Privacy Act which the releases affect. After reading the releases and the Privacy Act itself, I believe that the bargaining unit needs additional time sufficient to seek the advice of its counsel. Without such additional time to seek counsel and to communicate among its members, the bargaining unit is simply not able to inform itself adequately about the impact of the releases. Clearly, comments which are not adequately informed are not useful to the Commission, and also expose the bargaining unit to making unfounded representations at this point.

COMMENT 2: REQUEST FOR NEGOTIATION WITH THE UNION

I believe that the releases involve matters which are appropriate for consultation and negotiation between CFTC and the union. As provided by CFTC's agreement with the union, I request that CFTC honor its obligation to meet and confer with the union where matters are appropriate for

consultation and negotiation. I request that you treat this comment letter, standing alone, as a sufficient exercise of the union's request to meet and confer with CFTC with respect to the releases. To exercise further the union's right to meet and confer with CFTC in connection with the releases, I have provided a separate letter which expressly states the union's request in this regard. A copy of that separate letter, which is sent under separate cover to Mr. Donald Tendick, is attached for reference.

Thank you for your attention to these matters. I appreciate your response. Kindly note that my current address is 201 Varick Street, Room 903, New York, New York 10014-4811.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Steven Garitta".

Steven Garitta, President

American Federation of Government Employees--
Local 3477

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OFFICE OF THE SECRETARIAT

November 1, 1999

Mr. Donald Tendick, Acting Executive Director
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st St. NW
Washington, DC 20581

BY FIRST CLASS MAIL
RETURN RECEIPT REQUESTED
Z 153 856 985

Dear Mr. Tendick:

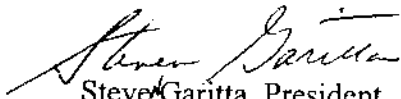
I submit this letter to you in my official capacity as the President of American Federation of Government Employees Local 3477 ("the union"). The union is the exclusive representative of all employees in the bargaining unit consisting of non-professional employees working in CFTC's Eastern Regional Office in New York City.

Federal Register release number 99-035 and Federal Register release number 99-036 ("the releases"), which the Commodity Futures Trading Commission ("CFTC") published in the Federal Register on September 30, 1999, provide for comments to be submitted in response to the releases. For purposes of commenting on the releases, I have submitted a comment letter which you will find enclosed.

My comment letter indicates that I am requesting that CFTC and the union meet and confer with respect to the releases. Consistent with my comment letter, under the heading **COMMENT 2: REQUEST FOR NEGOTIATION WITH THE UNION**, I believe that the releases involve matters which are appropriate for consultation and negotiation between CFTC and the union. As provided by CFTC's agreement with the union, I hereby request that CFTC honor its obligation to meet and confer with the union where matters are appropriate for consultation and negotiation.

Thank you for your attention to these matters. I appreciate your response. Kindly note that my current address is 201 Varick Street, Room 903, New York, New York 10014-4811.

Very truly yours,



Steve Garitta, President
American Federation of Government Employees--
Local 3477

cc:

By Hand Delivery with enclosures:
Mr. Marvin Jackson,
Regional Director, CFTC ERO

By CFTC Interoffice Mail with enclosures:
Ms. Marcia Scialdo,
Director of Human Resources, CFTC OHR

Special shift between Categories 338/339 and 638/639 is being reversed, and the current limits for these categories are being adjusted to reflect this change.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States** (see Federal Register notice 63 FR 71096, published on December 23, 1998). Also see 63 FR 67050, published on December 4, 1998.

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 27, 1999.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 30, 1998, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textiles and textile products and silk blend and other vegetable fiber apparel, produced or manufactured in the Philippines and exported during the twelve-month period which began on January 1, 1999 and extends through December 31, 1999.

Effective on October 4, 1999, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit ¹
Levels in Group 1	
338/339	2,851,226 dozen.
638/639	2,462,448 dozen.

¹The limits have not been adjusted to account for any imports exported after December 31, 1998.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Troy H. Cribb,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 99-25460 Filed 9-29-99; 8:45 am]

BILLING CODE 3510-DR-F

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974: Notice of New System of Records

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of new system of records and proposed routine uses.

SUMMARY: This notice adds a new system of records to the Commission's system of records under the Privacy Act. The new system will contain information about employees of the Commission and third parties who are visiting or working at Commission offices who are accused of sexual or other unlawful harassment. The Commission is proposing that the routine uses of these records be limited to use in proceedings in which the Commission or any present or former member or employee is a party and in any investigation to which the information is relevant. In addition, the Commission is proposing that the records be available to any other federal or state agency for use in meeting the responsibilities assigned to them under the law or to another federal agency, if relevant, in connection with a personnel action concerning the employee about whom the record is maintained. The Commission is also publishing a notice of a proposed rule to exempt the system of records under 5 U.S.C. 552a(k)(2) from certain sections of the Privacy Act, as investigatory material compiled for law enforcement purposes.

DATES: Comments on the establishment of the new system of records and the proposed routine uses must be received no later than November 1, 1999. The new system of records and the routine uses will be effective November 9, 1999 unless the Commission receives comments which would mandate a contrary determination.

ADDRESSES: Comments should be addressed to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW., Washington, DC 20581. Comments may be sent via electronic mail to secretary@cftc.gov.
FOR FURTHER INFORMATION CONTACT: Stacy Dean Yochum, Office of the Executive Director, (202) 418-5157, or Glynn L. Mays, Office of the General Counsel, (202) 418-5140, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, and the Commission's implementing regulations, 17 CFR part 146, the Commission is publishing a description of a new system of records. The new system will contain records generated in compliance with the Commission's Sexual Harassment Policy, which in relevant part permits persons

complaining of harassment to invoke certain informal procedures to resolve the complaint and requires a report of the resolution to be forwarded to the Commission's Executive Director. The Policy also requires supervisors and managers to report observed and reported incidents of harassment to the Commission's EEO Director. Under the Policy, reports or complaints of incidents of harassment if not resolved at the supervisor level may be referred in-house or to an outside contractor for investigation. These investigations may result in disciplinary action. This system also would contain similar records of complaints of other violations of equal employment rights, although the Commission does not have a published policy for informal handling of such matters at this time.

The system is being numbered "CFTC-7", the number used for a system of records which was consolidated with other systems and is no longer being maintained. This new system of records, as required by 5 U.S.C. 552a(f) of the Privacy Act, has been submitted to the Committee on Government Oversight and Reform of the U.S. House of Representatives, the Committee on Governmental Affairs of the U.S. Senate, and the Office of Management and Budget, pursuant to Appendix 1 to OMB Circular A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated July 15, 1994. Accordingly, the Commission is giving notice of the establishment of the following system of records:

CFTC-7

SYSTEM NAME:

Exempted Informal Employment Complaint Files.

SYSTEM LOCATION:

Office of the Executive Director, Three Lafayette Centre, 1155 21st St. NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, including Commission employees, contractors or visitors, who are accused of sexual or other harassment in violation of employment discrimination laws or Commission employment policies, including the Commission's Sexual Harassment Policy.

CATEGORIES OF RECORDS IN THE SYSTEM:

Reports to Commission officials from supervisors, managers, or members of the Commission concerning complaints or concerning observed instances of sexual harassment. Records relating to

the complaint or incident, relating to any investigation, and to any disposition of the matter. The potential contents of the system are not limited to complaints or other material under the Commission's Sexual Harassment Policy. Complaints concerning other forms of illegal employment discrimination would be made part of this system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:
5 U.S.C. 2302(b); 29 CFR 1614.102(a).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The four routine uses for this system are taken from the Commission's General Statement of Routine Uses, published 64 FR 33829: Number 1 (disclosed in an action where the Commission or a present or former member or employee of the Commission is a party); 2 (given to other federal or state agencies within the scope of their statutory mandates); 4 (disclosed in an investigation); and 6 (disclosed if relevant to a federal agency in connection with a personnel, contracting or licensing action concerning the person about whom the record is maintained).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records stored in files.

RETRIEVABILITY:

Records are retrievable by the name of the employee or third party about whom a complaint or report has been made.

SAFEGUARDS:

In addition to general building security, paper records are maintained in areas accessible only to authorized personnel.

RETENTION AND DISPOSAL:

Indefinite.

SYSTEM MANAGER(S) AND ADDRESS:

Executive Director, 1155 21st Street, NW, Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether the system of records contains information about themselves, seeking access to records about themselves in the system of records or contesting the content of records about themselves should address written inquiries to the Assistant Secretary for FOI, Privacy and Sunshine Acts Compliance, Commodity Futures Trading Commission, 1155 21st Street, NW, Washington, DC 20581.

RECORD ACCESS PROCEDURES:

See "Notification Procedures," above.

CONTESTING RECORD PROCEDURES:

See "Notification Procedures," above.

RECORD SOURCE CATEGORIES:

Internal complaints, internal investigations, reports of activity which apparently violate the Commission's Sexual Harassment Policy or other employment discrimination prohibitions, proceedings, as relevant, under the EEOC's Federal Sector Complaint Processing Rules, 29 CFR Part 1614.

(Authority: 5 U.S.C. 552a(e)(4))

Issued in Washington, DC, on September 22, 1999.

By the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 99-25190 Filed 9-29-99; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF DEFENSE

[OMB Control Number 0704-0321]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Contract Financing

AGENCY: Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), DoD announces the proposed extension of a public information collection requirement and seeks public comment on its provisions. DoD invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use through April 30, 2000, under OMB Control Number 0704-0321. DoD proposes that OMB extend its approval for use through April 30, 2003.

DATES: DoD will consider all comments received by November 29, 1999.

ADDRESSES: Interested parties should submit written comments and recommendations on the proposed information collection to: Defense Acquisition Regulations Council, Attn: Ms. Sandra Haberlin, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301-3062. Telefax (703) 602-0350.

Address E-mail comments submitted via the Internet to: dfars@acq.osd.mil.

Please cite OMB Control Number 0704-0321 in all correspondence related to this issue. E-mail comments should cite OMB Control Number 0704-0321 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra Haberlin, at (703) 602-0289. The information collection requirements addressed in this notice are available electronically via the Internet at: <http://www.acq.osd.mil/dp/dars/dfars.html>

Paper copies are available from Ms. Sandra Haberlin, PDUSD (A&T) (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301-3062.

SUPPLEMENTARY INFORMATION:

Title, Associated Form, and OMB Number: Contract Financing, Progress Payments for Foreign Military Sales Acquisitions—Defense Federal Acquisition Regulation Supplement (DFARS) Part 232 and the clause at 252.232-7002; OMB Control Number 0704-0321.

Needs and Uses: Section 22 of the Arms Export Control Act (22 U.S.C. 2762) requires the U.S. government to use foreign funds, rather than U.S. appropriated funds, to purchase military equipment for foreign governments. To comply with this requirement, the government needs to know how much to charge each country. The clause at 252.232-7002, Progress Payments for Foreign Military Sales Acquisitions, requires each contractor whose contract includes foreign military sales (FMS) requirements to submit a separate progress payment request for each progress payment rate, and to submit a supporting schedule that clearly distinguishes the contract's FMS requirements from U.S. requirements. The Government uses this information to determine how much of each country's funds to disburse to the contractor.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Annual Burden Hours: 9,234 (includes 3,078 response hours plus 6,156 recordkeeping hours).

Number of Respondents: 513.

Responses Per Respondents: 12.

an accommodation to members. The approach has been that it will not take exception to FCUs that permit overdrafts as long as there are no safety and soundness concerns or evidence that the practice is being abused or otherwise used as a means of circumventing other regulatory requirements or giving preferential treatment to insiders.

Finally, in proposing this rule, NCUA is not directing or encouraging credit unions to replace using written overdraft agreements with members with a written overdraft policy. In fact, because written overdraft agreements function essentially as a lending agreement that becomes operational in the event of an overdraft, they are a preferable way of addressing the safety and soundness concerns presented by overdrafts.

B. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any proposed regulation may have on a substantial number of small entities (primarily those under \$1 million in assets). The NCUA has determined and certifies that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small credit unions. Accordingly, the NCUA has determined that a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

The NCUA Board has determined that the proposed notice and disclosure requirements in § 701.21 constitute a collection of information under the Paperwork Reduction Act. NCUA is submitting a copy of this proposed rule to the Office of Management and Budget (OMB) for its review.

The proposed rule requires a federal credit union that advances money to a member to cover his or her account deficit without having the member's credit application on file to have a written overdraft policy. The policy must: (1) Address how the credit union will honor overdrafts; (2) set a cap on the total dollar amount of all overdrafts the credit union will cover; (3) establish time limits for a member to deposit funds to cover each overdraft; (4) limit the number and dollar amount of overdrafts the credit union will honor per member; and (5) establish the fee and interest rate, if any, the credit union will charge members for covering overdrafts.

The written policy requirement is necessary to insure safety and soundness in the credit union industry and protect the interests of credit union members where a federal credit union provides overdraft protection to a member without having his or her credit application on file.

The NCUA Board estimates that it will take an average of four hours to comply with this written policy requirement. The NCUA Board also estimates that 1000 federal credit unions will write overdraft policies so the total annual collection burden is estimated to be approximately 4000 hours.

The Paperwork Reduction Act of 1995 and OMB regulations require that the public be provided an opportunity to comment on information collection requirements, including an agency's estimate of the burden of the collection of information. The NCUA Board invites comment on: (1) Whether the collection of information is necessary; (2) the accuracy of NCUA's estimate of the burden of collecting the information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collection of information. Comments should be sent to: OMB Reports Management Branch, New Executive Office Building, Room 10202, Washington, D.C. 20503; Attention: Alex T. Hunt, Desk Officer for NCUA. Please send NCUA a copy of any comments you submit to OMB.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. This proposed rule makes no significant changes with respect to state credit unions and therefore, will not materially affect state interest.

C. Agency Regulatory Goal

NCUA's goal is clear, understandable regulations that impose a minimal regulatory burden. We request your comments on whether the proposed amendment is understandable and minimally intrusive if implemented as proposed.

List of Subjects in 12 CFR Part 701

Credit, Credit unions, Reporting and recordkeeping requirements

By the National Credit Union Administration Board on September 16, 1999.

Becky Baker,
Secretary of the Board.

For the reasons set forth in the preamble, the National Credit Union Administration proposes to amend 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, and 1789.

Section 701.6 is also authorized by 15 U.S.C. 3717.

Section 701.31 is also authorized by 15 U.S.C. 1601 et seq.; 42 U.S.C. 1991 and 3601-3610.

Section 701.35 is also authorized by 42 U.S.C. 4311-4312.

2. Amend § 701.21 by revising paragraph (c)(3) to read as follows:

§ 701.21 Loans to members and lines of credit to members.

* * * * *

(c) * * *

(3) *Credit applications and overdrafts.* Consistent with policies established by the board of directors, the credit committee or loan officer shall ensure that a credit application is kept on file for each borrower supporting the decision to make a loan or establish a line of credit. A credit union may advance money to a member to cover an account deficit without having a credit application from the borrower on file if the credit union has a written overdraft policy. The policy must: address how the credit union will honor overdrafts; set a cap on the total dollar amount of all overdrafts the credit union will honor consistent with the credit union's ability to absorb losses; establish a time limit not to exceed ten business days for a member either to deposit funds or obtain an approved loan from the credit union to cover each overdraft; limit the number and dollar amount of overdrafts the credit union will honor per member; and establish the fee and interest rate, if any, the credit union will charge members for honoring overdrafts.

* * * * *

[FR Doc. 99-25397 Filed 9-29-99; 8:45 am]

BILLING CODE 7535-01-U

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 146

Privacy Act of 1974; Implementation

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to adopt a rule to exempt a new system of records, concerning, *inter alia*, complaints of sexual harassment, from

Sections 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act of 1974 on the basis that the system is investigatory material compiled for law enforcement purposes. The name of the system of records is the Exempted Informal Employment Complaint Files and it is designated CFTC-7.

DATES: Comments must be received on or before November 1, 1999.

ADDRESSES: Comments should be addressed to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1152 21st Street NW., Washington, DC 20581. Comments may also be sent by facsimile to number (202) 418-5221 or by electronic mail to secretary@cftc.gov. Refer to "Sexual harassment files."

FOR FURTHER INFORMATION CONTACT: Stacy Dean Yochum, Counsel to the Executive Director, (202) 418-5157, Glynn L. Mays, Office of the General Counsel, (202) 418-5140, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: In September 1998 the Commission adopted a Sexual Harassment Policy that enabled persons who believed they were victims of harassment to invoke certain informal procedures. The Policy requires all supervisors, managers, and members of the Commission to report instances of sexual harassment witnessed by them or reported to them to the Commission's EEO Director. Remedies under the Policy include methods for informal resolution of complaints between a complainant and the person she or he believes has engaged in harassment and also for investigations under the aegis of the Executive Director to determine whether disciplinary action is warranted. Records of complaints, reports, investigations, and dispositions will be maintained by the Executive Director. The purposes of the records system include centralization information on this workplace issue and the Commission's response to it, identification of repeat offenders, and support for disciplinary action. Neither the Policy nor the system of records is part of the EEOC's Federal Sector Complaint Processing system. See 29 CFR part 1614. Both the policy and maintenance of the system of records are, however, consistent with the EEOC's mandate to federal agencies to "maintain a continuing affirmative program to promote equal opportunity and to identify and eliminate discriminatory practices and policies." 29 CFR 1614.102(a).

In the Commission's view, the materials in this system of records are investigatory materials compiled for law enforcement purposes within the meaning of Privacy Act Section 552a(k)(2), 5 U.S.C. 552a(k)(2). Individual access to these files could impair the effectiveness and orderly conduct of the Commission's program to combat illegal workplace discrimination and discipline those responsible.

Accordingly the Commission is proposing to amend its rules under the Privacy Act, 17 CFR 146.12, to exempt this system of records from the requirements of Privacy Act sections 552a(c)(3) [availability of accounting of disclosures]; (d) [individual access to records]; (e)(1) [relevancy of records]; (e)(4)(G) [request of an individual whether a system of records contains a record pertaining to him or her]; (e)(4)(H) [notification of access and contest procedures]; (e)(4)(I) [publication of categories of sources of records in the system]; and (f) [adoption of rules relating, *inter alia*, to individual access to his or her records in the system].

List of Subjects in 17 CFR Part 146

Privacy.

For the reasons stated above, the Commodity Futures Trading Commission proposes to amend 17 CFR part 146 as follows:

PART 146—RECORDS MAINTAINED ON INDIVIDUALS

1. The authority citation for part 146 continues to read as follows:

Authority: Pub. L. 93-579, 88 Stat. 1896 (5 U.S.C. 552a), Pub. L. 93-463, 88 Stat. 1389 (7 U.S.C. 40(j)) unless otherwise noted.

2. Amend § 146.12 Exemptions, by revising the last sentence of paragraph (a) to read as follows:

§ 146.12 Exemptions.

(a) * * * Materials exempted under this paragraph are contained in the system of records entitled "Exempted Investigatory Records," "Exempted Informal Employment Complaint Files," and/or in the system of records entitled "Exempted Closed Commission Meetings."

* * * * *

Issued in Washington, DC, on September 22, 1999.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 99-25189 Filed 9-29-99; 8:45 am]

BILLING CODE 8351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210, 211, 820, and 1271

[Docket No. 97N-484S]

Suitability Determination for Donors of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations to require manufacturers of human cellular and tissue-based products to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable disease agents and diseases. Human cellular and tissue-based products are products that contain or consist of human cells or tissues and that are intended for implantation, transplantation, infusion, or transfer. As part of this regulatory action, the agency is proposing to amend the current good manufacturing practice (CGMP) regulations that apply to human cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor-suitability procedures into existing good manufacturing practice (GMP) regulations. The agency is taking this action to provide more appropriate oversight for the wide spectrum of human cellular and tissue-based products that are marketed now or may be marketed in the future. The agency's action would improve protection of the public health and increase public confidence in new technologies, while permitting significant innovation and keeping regulatory burden to a minimum.

DATES: Submit written comments on the proposed rule on or before December 29, 1999. Submit written comments on the information collection provisions on or before November 1, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503. Attn: Wendy Taylor, Desk Officer for FDA.