(c) In no case shall a State refuse to pay relocation payments for homeowners who were allowed temporary occupancy while awaiting for replacement property.

(e) An owner of a single-family residence who elects to retain a right of use and occupancy for not less than six months from date of acquisition of such residence shall be informed that any benefits to which he/she may be entitled under sections 203, 204, 205, and 206 of the Act will be deemed to have been waived as a result of such use and occupancy.

§ 916.117 Appeal procedure.

Prior to approving any federally assisted project, heads of Offices administering federally assisted programs or projects which will result in the displacement of persons shall require the State agency to furnish a description of the appeal procedures that are available to such displaced persons, to assure that any person aggrieved by a determination as to eligibility for a payment authorized by the Act or the amount of a payment, may have his/her application reviewed by the head of the State agency.

Subpart K—Administrative Review and Appeals

§ 916.120 Compliance reviews.

The head of each Office engaged in NOAA programs or federally assisted programs administered by NOAA which involve the acquisition of real property and/or the displacement of persons shall provide for such periodic review of the operations at regional and other field office levels as he/she deems necessary to insure proper implementation of, and full compliance with, the provisions of the Act and the regulations in Part 930–50.

§ 916.121 Appeals.

All eligible relocatees shall be furnished a written notice of their right to appeal. Such notification may be provided by brochure if the right to appeal is adequately described therein.

§ 916.122 Appeal procedure.

In NOAA acquisition programs any dispute concerning a question arising under the Act which is not disposed of by agreement shall be decided by the head of the Office who shall reduce his decision to writing and mail a copy thereof to the displaced person. This decision shall be final and conclusive unless, within 30 days from date of mailing of such copy, the displaced person mails a written appeal addressed to the Administrator, National Oceanic and Atmospheric Administration, Rockville, Maryland, in accordance with the regulations in 43 CFR Part 4, Subpart G. The decision of the Administrator shall be final and conclusive. In connection with any appeal to the Administrator, the displaced person may be afforded an opportunity to be heard and to offer evidence in support of his appeal, as provided for in 43 CFR Part 4, Subpart G.

Subpart L—Annual Report

§ 916.125 General.

Each Office having responsibilities for Federal or federally assisted programs that come within the purview of Public Law 91–646 shall prepare and submit an annual report to the Administrator, NOAA on its activities related to programs and policies established or authorized by the Act. This report, which is required by section 214 of the Act, shall consist of both a narrative and statistical report.

§ 916.126 Narrative report.

The narrative portion of the report should be consolidated for the Office and submitted, in duplicate, in the form of an attachment to a transmittal memorandum. It shall respond to each of the items set out in the following subparagraphs as the item pertains to the respective Office. Narrative comments should be furnished for all items. If an item is not applicable to an Office, or if a negative response pertains to a particular item, the report should so indicate.

(a) Assurance of required replacement housing.

(1) Each Office should comment on the effectiveness of the provisions of the Act relating to assurances of the availability of comparable decent, safe, and sanitary replacement housing for displaced homeowners and tenants.

(2) Describe the actions taken by the Office to assure compliance with the requirements of sections 205(c)(3), 206(b), and 210(3) of the Act.

(3) Provide information on all court decisions affecting the Office which concern the adequacy of replacement housing.

(b) Office actions to achieve objectives of the Act.

(1) Describe the actions taken by the Office to achieve the objectives of the policies of the Congress to provide uniform and equal treatment, to the greatest extent practicable, for all persons displaced by or having real property taken for Federal or federally assisted programs.

(2) Describe the provisions adopted by the Office for coordination with other Federal, State and local displacing agencies.

(c) Progress in achieving objectives of the Act. Report the progress of the Office in the various programs conducted or administered, indicating:

(1) The success in coordinating Office relocation activities with other Federal, State, and local agencies.

(2) Office experience and the cost of utilization of authority under section 206(a) of the Act to provide replacement housing, citing difficulties, if any, in obtaining funds for this purpose and the impact on specific projects.

(3) Office experience and cost of implementing section 215 of the Act, concerning loans for planning and obtaining federally insured mortgage financing for replacement housing.

(4) For federally assisted programs administered by the Office, enumerate the States not in compliance with the Act or the reporting date. If compliance by any State does not extend to any or all federally assisted programs conducted or administered by the Office, the programs excepted should be indicated and an explanation furnished for the basis of the State's inability to comply. In all such instances, indicate the expected date for full compliance by the state.

(5) Describe adverse effects of the Act, if any, on programs conducted by the Office.

(d) Effect of Act on the public. Describe any indicated effects of the relocation program and policies on the public, reporting conclusions obtained from surveys, special studies, and other sources relating to the effects of implementation of the Act on a neighborhood or community.

(e) Recommendations. Furnish any recommendations for further improvement in relocation assistance and land acquisition programs, policies, and implementing laws and regulations. Include any proposals for amendments or revisions to:

(1) General Services Administration Guidelines.

(2) Federal legislation.

(3) State legislation.

(f) Waiver of assurances of replacement housing. Describe any situations or circumstances which required a waiver of assurance of replacement housing pursuant to subsection 205(c)(3) of the Act. For any waivers reported, submit the Office findings and determination supporting waiver of the requirements of the subsection.

§ 916.127 Statistical report.

The statistical portion of the report shall be submitted on General Services Administration Form 2997. The forms should be consolidated for the Office and submitted in duplicate. Those Offices administering both Federal and federally assisted programs shall submit separate consolidated forms for such programs.

§ 916.128 Submission.

The annual report shall be prepared on a fiscal year basis and submitted in duplicate to reach the Administrator, NOAA, by not later than September 1 of each year.

[FR Doc.76-27649 Filed 9-21-76;8:45 am]

Title 19—Customs Duties

CHAPTER I—UNITED STATES CUSTOMS SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 76-267]

PART 113—CUSTOMS BONDS

Landing Bond for Alcoholic Beverages

Section 113.14 of the Customs Regulations (19 CFR 113.14), which lists the types of bonds subject, after execution, to approval by a district director of Customs, includes in paragraph (r) (19 CFR 113.14(r)) the landing bond for alcoholic beverages. Section 113.14(r) of the Customs Regulations describes the bond in question as "Landing Bond, Customs

Form 7593, or landing bond in the form prescribed in T.D. 47886."

It has come to the attention of the United States Customs Service that the wording of § 113.14(r) of the Customs Regulations, suggests that Customs Form 7593 is a different document from the landing bond prescribed in Treasury Decision 47886. Actually, Treasury Decision 47886 provided that the form prescribed therein was "to be designated Customs Form 7593." However, Customs Form 7593 has never been printed by the Government Printing Office or otherwise been made available by the Customs Service. Instead, persons needing to file a landing bond for alcoholic beverages have been referred to Treasury Decision 47886, which requires that a bond be filed in substantially the form prescribed therein.

Accordingly, in order to eliminate any continued confusion in this matter, paragraph (r) of § 113.14 of the Customs Regulations (19 CFR 113.14(r)) is amended to read as follows:

§ 113.14 Bonds approved by the district director.

* * * * *

(r) *Landing bond for alcoholic beverages.* Landing bond, in the form prescribed in T.D. 47886, to land spirits, wines, or other alcoholic liquors in foreign ports, in an amount equal to double the estimated duty.

* * * * *

(R.S. 251, as amended, sec. 623, 624, 46 Stat. 759, as amended (19 U.S.C. 66, 1623, 1624))

Because this amendment merely clarifies present requirements and requires no public initiative, notice and public procedure thereon is found to be unnecessary and good cause exists for dispensing with a delayed effective date under the provisions of 5 U.S.C. 553.

Effective date: This amendment shall become effective September 22, 1976.

LEONARD LEHMAN,
Acting Commissioner of Customs.

Approved: September 10, 1976.

DAVID R. MACDONALD,
Assistant Secretary of the Treasury.

[FR Doc.76-27778 Filed 9-21-76;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

[Docket No. 75F-0270]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS; RESINOUS AND POLYMERIC COATINGS FOR POLYOLEFIN FILMS

The Food and Drug Administration is amending the food additive regulations to provide for the use of a 2-sulfoethyl methacrylate, sodium salt as a component of coatings for use in contact with food, and to provide for the use of N,N'-diphenyl-p-phenylenediamine as a polymerization inhibitor for 2-sulfoethyl methacrylate, sodium salt; effective September 22, 1976; objections by October 22, 1976.

Notice was given by publication in the FEDERAL REGISTER of October 29, 1975 (40 FR 50299) that a petition (FAP 5B3112) had been filed by the Morton Chemical Co., 110 North Wacker Drive, Chicago, IL 60606, proposing that §§ 121.2526 and 121.2569 (21 CFR 121.2526 and 121.2569) be amended to provide for the use of 2-sulfoethyl methacrylate, sodium salt as a component of coatings in contact with food.

The Commissioner of Food and Drugs, having evaluated data in the petition and other relevant material, concludes that §§ 121.2526 and 121.2569 should be amended as set forth below to provide for the use of the petitioned additive and to provide for the use of *N,N'*-diphenyl-*p*-phenylenediamine, currently regulated in other food additive regulations, as a polymerization inhibitor for the additive.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat 1786 (21 U.S.C. 348(c)(1)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 121 is amended in Subpart F as follows:

1. Section 121.2526 is amended in paragraph (b)(2) by alphabetically adding 2 new items as follows:

§ 121.2526 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * * * *

(b) * * *
(2) * * *

* * * * * * *

List of substances	*Limitations*
* * * * * * *	
N,N'-Diphenyl-*p*-phenylenediamine.	For use only as polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
* * * * * * *	
2-Sulfoethyl methacrylate, sodium salt [C.A. Registry No. 10595-80-9].	For use only in copolymer coatings under conditions of use E, F, and G described in paragraph (c) of this section, table 2, and limited to use at a level not to exceed 1.0 percent by weight of the dry copolymer coating.
* * * * * * *	

2. Section 121.2569 is amended in paragraph (b)(3) by alphabetically adding 2 new items as follows:

§ 121.2569 Resinous and polymeric coatings for polyolefin films.

* * * * * * *

(b) * * *
(3) * * *

List of substances	*Limitations*
* * * * * * *	
N,N'-Diphenyl-*p*-phenylenediamine.	For use only as a polymerization inhibitor in 2-sulfoethyl methacrylate, sodium salt.
* * * * * * *	
2-Sulfoethyl metacrylate, sodium salt [C.A. Registry No. 10595-80-9].	For use only in copolymer coatings under conditions of use E, F, and G described in table 2 of § 121.2526(c) and limited to use at a level not to exceed 1.0 percent by weight of the dry copolymer coating.
* * * * * * *	

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 22, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date: This regulation shall become effective September 22, 1976.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1)).)

Dated: September 15, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-27664 Filed 9-21-76;8:45 am]

PART 121—FOOD ADDITIVES

Subpart F—Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food

ADHESIVES; STYRENE BLOCK POLYMERS

The Food and Drug Administration is amending the food additive regulations to provide for the use of styrene block polymers with 1,3-butadiene as a component of food-packaging adhesives; effective September 22, 1976; objections by October 22, 1976.

Notice was given by publication in the FEDERAL REGISTER of November 20, 1975 (40 FR 50422), that a petition (FAP 6B3156) had been filed by the Minnesota Mining and Manufacturing Co., 3M Center, St. Paul, MN 55101, proposing that §§ 121.2520, 121.2622, and 121.2577 (21 CFR 121.2520, 121.2622, and 121.2577) be amended to provide for the safe use of the subject additive as a component of adhesives and pressure-sensitive adhesives intended to contact food. The petitioner subsequently amended the petition to delete the request for the pressure-sensitive adhesive coverage (§ 121.2577).

The Commissioner, having evaluated data in the petition and other relevant material, concludes that §§ 121.2520 and 121.2622 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1 (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 121 is amended as follows:

1. By amending § 121.2520(c)(5) by alphabetically adding a new item to the list of substances, to read as follows:

§ 121.2520 Adhesives.

* * * * *

(c) * * *

(5) * * *

COMPONENTS OF ADHESIVES

Substances	*Limitations*
* * * * *	
Styrene block polymers with 1,3-butadiene.	
* * * * *	

2. By adding new paragraph (e) to § 121.2622 to read as follows:

§ 121.2622 Styrene block polymers.

* * * * *

(e) The provisions of this section are not applicable to styrene block polymers with 1,3-butadiene listed in § 121.2520.

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 22, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Six copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date: This regulation shall become effective September 22, 1976.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348 (c)(1)).)

Dated: September 15, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-27666 Filed 9-21-76;8:45 am]

SUBCHAPTER F—BIOLOGICS

[Docket No. 76N-0022]

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

Test for Pyrogenic Substances

The Food and Drug Administration (FDA) is amending the biologics regulations in § 610.13 (21 CFR 610.13), which governs the test for pyrogenic substances, effective September 22, 1976.

In a proposed regulation published in the FEDERAL REGISTER of June 10, 1974 (39 FR 20399), the Commissioner of Food and Drugs proposed to amend paragraph (b) of § 610.13 Purity, to update the test for pyrogenic substances to include improved procedures developed since its incorporation into the biologics regulations on June 30, 1960. The pyrogen test is designed to establish whether a biological product is free from fever-producing contaminants and impurities, which, if present, may result in illness and death to the user. The proposed regulation included most of the provisions of the pyrogen test method published in the United States Pharmacopeia (U.S.P.), which is more specific on test procedures, number of test animals to be used, and interpretation of results. The proposed regulation thus provided a method of testing for pyrogens that is comparable to the method used for testing all other drugs for human use.

Interested persons were given until August 9, 1974 to file written comments with the Hearing Clerk, Food and Drug Administration. Eight letters about the proposal were received. Their comments and the Commissioner's responses are as follows:

1. Two comments concerned the proposal's preamble and statements therein that implied that the rabbit pyrogen test is the best current scientific testing procedure. One comment requested data demonstrating that the rabbit test is the most reliable test. The other comment stated that the Limulus Amebocyte Lysate test is superior to the rabbit pyrogen test and should be permitted as an alternate test, or the rabbit test should be used only as a reference test and not as the required procedure.

The Commissioner advises that practical experience with the rabbit test accumulated through the years by the Bureau of Biologics and manufacturers' control laboratories indicates that, with the exception of a limited number of lots of 25 percent Normal Serum Albumin (Human), the rabbit pyrogen test reliably detects pyrogenic substances in biological products. Furthermore, a number of studies published in the scientific literature demonstrate the effectiveness of the rabbit test for detecting pyrogenic substances. These studies are available at the office of the Hearing Clerk, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

The Commissioner is aware of the potential value of the Limulus Amebocyte Lysate test to detect bacterial endotoxins as pyrogens in human blood and in drugs for human use. He is receptive to licensing the reagents for the Limulus Amebocyte Lysate Test provided adequate data are received to support the stability of the lysate material, consistency in production, and relative effectiveness of the Limulus Amebocyte Lysate test to the current rabbit test. To date, adequate data have not been received to support licensing of the reagents. When adequate data are received, the reagents for the Limulus Amebocyte Lysate test will be licensed and products that can be tested by this method will be prescribed. In addition, the pyrogen test method in § 610.13(b) can be amended to permit the use of the Limulus Amebocyte Lysate test for certain products. Until such time, the rabbit test must continue to be the required test for pyrogens, and no change is made in the final regulation.

2. Two comments indicated that the test dose volume prescribed in the U.S.P. is inconsistent with the test dose volume in existing § 610.13(b)(1). (On July 1, 1975, subsequent to the proposal and comment period for this regulation, the nineteenth revision, U.S.P. XIX, became official. Discussion in this preamble will reference the requirements of this current official edition.)

Although the proposal did not contain an amendment to § 610.13(b)(1), the Commissioner will, however, respond to the comment.

The U.S.P. XIX prescribes a test dose volume of 10 milliliters per kilogram of body weight of the rabbit; the current § 610.13(b)(1) prescribes at least 3 milliliters and need not exceed 10 milliliters per kilogram of body weight of the rabbit

and also requires that the test dose volume be equivalent proportionately, on a body weight basis, to the maximum single human dose. The Commissioner did not intend to revise the test dose volumes specified in § 610.13(b)(1) to make them consistent with the test dose volumes prescribed in U.S.P. XIX because the test dose volumes prescribed in § 610.13(b)(1) have been established experimentally over the years to be the maximum volume that can be safely tolerated by rabbits and still detect the presence of pyrogenic substances in biological products. However, there should be no inconsistency in practice between the U.S.P. and the biologics regulations since for biological pharmacopeial drugs "revisions of the federal requirements affecting the USP monographs will be made the subjects of USP Supplements" (U.S.P. XIX, "Biologics," p. 675). Moreover, both the U.S.P. XIX in its individual monographs and the biologics regulations in § 610.13(b)(1) provide exceptions to the general test dose volumes prescribed. All biological products requiring pyrogen testing are derived from protein of animal species other than the rabbit. In addition, the concentration of protein varies from one product to another. If the test dose volumes were adjusted to be consistent with the volume specified in the general procedure in U.S.P. XIX, many rabbits would die as a result of the injection of foreign protein in volumes and concentrations that could not be tolerated by the rabbits. It is apparent that such a test dose volume requirement would not be compatible with a valid test for detection of pyrogenic substances. Accordingly, no change is made in the current § 610.13(b)(1).

3. One comment suggested that the U.S.P. XIX requirement that equipment be rendered pyrogen-free by heating to 250° C be included as a requirement of the pyrogen test in § 610.13.

The Commissioner recognizes the need to render all testing equipment pyrogen-free. Failure to do so could cause a positive test suggesting the presence of pyrogens in the product rather than in the equipment used for performing the test. Under these circumstances the lot would fail the test and would not be released. The preparation of equipment before testing is only one of several preparatory steps required before performing the test. Section 610.13 is intended to describe the required test method; it is not intended to describe all the quality control procedures and appropriate precautions required to assure validity of the test. Accordingly, no change is made in the final regulation.

4. One comment concerning proposed § 610.13(b)(2) asked for clarification of the phrase "overtly healthy."

The Commissioner has used the phrase as a general term to prevent the use of obviously sick rabbits, even when the temperature of the rabbit falls within the temperature requirements of § 610.13(b)(2).

5. Two comments suggested that proposed § 610.13(b)(2) include a requirement that rabbits weigh not less than 1,500 grams, to be consistent with the U.S.P. XIX requirement for test animals.

The Commissioner did not prescribe a minimum weight requirement so that dwarf breeds of rabbits that may weigh less than 1,500 grams at maturity could be used. Dwarf breeds of rabbits may be economically advantageous to use because they require less space for housing. The 1,500-gram minimum weight requirement prescribed by U.S.P. XIX is intended to prohibit the use of juvenile rabbits. In this respect, the first sentence of § 610.13(b)(2) prescribes the use of mature rabbits, which is consistent with the intent of the U.S.P. XIX requirement. Accordingly, no change is made in the regulation.

6. Two comments concerning proposed § 610.13(b)(2) questioned the advisability of permitting re-use of animals for pyrogen testing.

The Commissioner recognizes that re-use of rabbits within 2 weeks following a pyrogenic reaction is not desirable because rabbits exposed to pyrogenic substances may become refractive and fail to react on subsequent exposure to pyrogenic substances. The prescribed rest of 2 weeks for rabbits given a test sample that was adjudged pyrogenic is intended to allow sufficient time to avoid the period during which the rabbit can be refractive. On the other hand, manufacturers of blood derivatives have avoided the re-use of a rabbit with products containing similar proteins for fear of obtaining spurious results. The question concerning re-use of rabbits for pyrogen testing has been the subject of extensive discussion within the scientific community. On the basis of data available at the present time, there is no reason to prohibit re-use of rabbits for pyrogen testing. Nevertheless, the Commissioner encourages interested persons to submit data from controlled studies for further consideration, and if the data demonstrate that re-use of rabbits is contraindicated, the regulation will be amended to prohibit their re-use.

7. One comment concerning proposed § 610.13(b)(2) objected to requiring a "sham test" on a rabbit previously used in a pyrogen test.

The sham test is a procedure used to condition rabbits before pyrogen testing. Those rabbits that are not preconditioned may become excited during testing and produce irregular temperature responses, causing a false-positive reading. The Commissioner agrees that a rabbit conditioned for the initial pyrogen test may remain adequately docile for all further pyrogen tests, and that the requirement to condition all re-use rabbits in a sham test would then be unnecessary. Accordingly, paragraph (b)(2) is revised to require that only rabbits being used in a pyrogen test for the first time need be conditioned by a sham test.

8. Two comments concerning proposed § 610.13(b)(2) related to the requirement that food be withheld from rabbits on the day of the test until completion of the test. One comment stated that the U.S.P. XIX requires that food be withheld only during the test. The other comment stated that a literal interpretation of "the day of the test" would mean starting at midnight.

The Commissioner intended that food be withheld from rabbits only during the test, and the final regulation is amended accordingly.

9. One comment on proposed § 610.13(b)(2) concerned the requirement that the control temperature of a rabbit be obtained by allowing sufficient time for the temperature-measuring device to reach a maximum temperature before taking the reading. The comment stated that the requirement is inconsistent with the U.S.P. XIX requirement that an accurate clinical thermometer, for which the time necessary to reach the maximum reading is known, be used.

The Commissioner finds no inconsistency between these requirements. The intent of both requirements is that the temperature of the rabbits be accurately determined. The proposed regulation requires that the temperature-measuring device remain in the animal for a sufficient time necessary to reach maximum temperature. The time necessary may be known, or it may be determined before testing.

10. Two comments concerning proposed § 610.13(b)(2) related to the requirement that the test dose be injected at the rate of not less than 1 milliliter per minute rather than injection of the test dose within 10 minutes, as prescribed in the U.S.P. XIX. One comment requested an explanation for selecting 1 milliliter per minute as the injection rate. The other comment recommended reconciling the proposed testing procedure with that found in the U.S.P. XIX and cited the injection rate in U.S.P. XIX to be within 40 minutes.

The Commissioner proposed that the test dose be injected at the rate of not less than 1 milliliter per minute when the then current U.S.P. XVIII required that the test dose be injected within 40 minutes. The volume of test dose required for many biological products is approximately 1 to 3 milliliters, and the injection of small volumes over 40 minutes would not provide sufficient stress to the test animal to produce a meaningful test. On July 1, 1975, the U.S.P. XIX became official, and the rate of injection was changed to require injection of the test dose within 10 minutes after start of administration. The Commissioner is of the opinion that the rate recommended in U.S.P. XIX is compatible with the small and larger volume test doses required for biological products; and therefore, paragraph (b)(2) of § 610.13 is changed in the final regulation to agree with the U.S.P. XIX procedure. The comment citing the U.S.P. XIX injection rate to be within 40 minutes was apparently a misstatement.

11. Two comments concerning proposed § 610.13(b)(2) and (3) suggested that the interpretation of test results be expressed in positive terms, i.e., passing the test rather than in negative terms, i.e., failing the test.

The Commissioner agrees with these suggestions. The general safety test (21 CFR 610.11) and sterility test (21 CFR 610.12) prescribed in the general standards for most biological products, as well as many tests prescribed in the additional standards for specific biological products, express interpretation of test results in terms of passing the test rather than failing the test. For consistency, paragraphs (b)(2) and (3) are changed accordingly in the final regulation.

12. Two comments concerning proposed § 610.13(b)(2) objected to the requirement that to pass the initial test none of the three rabbits tested may produce a temperature rise of 0.6° C or more. Both comments indicated that the lot should pass the test if one of the three rabbits tested produces a temperature rise of 0.6° C, as prescribed in the current § 610.13(b)(3). One of the comments suggested that the criteria for passing the initial test are inconsistent with the criteria prescribed in the proposed paragraph (b)(3) for passing the retest. Namely, to pass the initial test none of the three rabbits may show a rise of 0.6° C, however, three of the eight rabbits from the initial and repeat tests combined may show a temperature rise above 0.6° C. The other comment concluded that the proposed revision would probably increase the retest rate and fail occasional lots of pyrogen-free products, thereby increasing the cost of the product to users without providing increased assurance of a safe product.

The Commissioner is of the opinion that all drugs for human use should be subject to the same criteria of acceptance with respect to the pyrogen test. In this respect, the proposed criteria for passing the test are the same as those prescribed in the U.S.P. XIX. In addition, experimental data indicate that in comparative tests, the threshold doses of bacterial endotoxin are approximately equal in rabbit and man. However, as the dose increases, the reaction is more severe in man than in the rabbit. Consequently, borderline reactions in the rabbit must be considered as potentially more reactive in man, and therefore the more sensitive criteria of the proposed § 610.13(b) (2) and (3) are justified. The requirement that all three rabbits pass the initial test is consistent with the U.S.P. XIX requirement for passing the initial test. If limited testing is to be done, it is consistent with other biological screening tests to expect no failures in the initial testing. If there are any failures in the initial testing it is consistent with U.S.P. XIX and other biological screening tests to repeat the tests using a larger sample, in this case five additional rabbits. The results of all tests must be considered in evaluating a lot for release. Accordingly, the Commissioner rejects the suggestion that the lot of product should pass the initial test if one of the three rabbits tested produces a temperature rise of 0.6° C. The Commissioner also rejects the suggestion that the proposed revision would probably increase the retest rate and fail occasional lots of pyrogen-free products. Rather, the proposed revision will encourage testing laboratories to take adequate precautions designed to minimize false-positive pyrogen test results, thereby reducing the retest rate. Accordingly, no change is made in the final regulation.

13. Three comments recommended that additional repeat tests should be permitted if the product fails to meet the requirements for retesting in proposed § 610.13(b)(3). One of the comments further indicated that the restriction permitting only one repeat test is inconsistent with the U.S.P. XIX requirements.

The Commissioner finds no basis for permitting an additional repeat test if the product fails both the initial pyrogen test as well as the retest. The current regulations permit an unlimited number of retests. Data available to the Commissioner resulting from such additional retesting reflect that only in a few isolated instances did a lot fail the initial and retest requirements, and pass subsequent retesting. The Commissioner believes that a scientifically sound pyrogen test procedure should include the use of a uniform number of rabbits to determine the presence of pyrogenic substances in each lot of product being tested. Furthermore, there is no provision in the U.S.P. XIX that permits use of more than a total of eight rabbits. The Commissioner is of the opinion that the manufacture of products should be sufficiently consistent so that each lot will pass applicable tests within a prescribed number of retests or replicate tests. The suggestion that more than one pyrogen retest be permitted is rejected, and no change is made in the final regulation.

The Commissioner has reviewed the potential environmental impact of the regulation and has concluded that the action will not significantly affect the quality of the human environment and that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 610 is amended in § 610.13 by revising paragraph (b)(2) and (3) to read as follows:

§ 610.13 **Purity.**

* * * * *

(b) * * *

(2) *Procedure; test results; standards to be met.* Use only overtly healthy mature rabbits. House the rabbits individually in an area of uniform temperature (±3° C), free from disturbances likely to excite them. Rabbits for pyrogen tests may not be used within 2 weeks following their having been given a test sample that was adjudged pyrogenic, and in no case may a rabbit be used more frequently than every 48 hours. Before using a rabbit that has never been used in a pyrogen test, condition it by a sham test that includes all the steps prescribed in paragraph (b)(2) of this section, except injection of the test dose. Perform the test under environmental conditions similar to those under which the rabbits are housed. During the test withhold all food, except water, from the rabbits. Determine the control temperature of each rabbit not more than 40 minutes before injecting the test dose. The control temperature is determined by inserting the temperature measuring device into the rectum of the test rabbit to a depth of not less than 7.5 centimeters and allowing sufficient time to reach a maximum temperature before taking the reading. The control temperature recorded for each rabbit constitutes the temperature from which any subsequent rise following the injection of the material is calculated. If the rectal temperature measuring device is to remain inserted throughout the testing period, restrain the rabbits in a manner that will allow them to assume a natural resting position. In any one test, use only those rabbits whose control temperatures do not deviate more than 1° C from each other, and do not use any rabbits with a temperature exceeding 39.8° C. Warm the test product to approximately 37° C, and inject the test dose into an ear vein of each of three rabbits. Injection of each test dose shall be completed within 10 minutes after the start of administration. Record the temperature of each rabbit at 1, 2, and 3 hours subsequent to the starting time of each injection. The lot meets the requirements for absence of pyrogens if no rabbit shows a rise in temperature of 0.6° C or more above its respective control temperature at any time period, and if the sum of the three rabbits' individual maximum temperature rises does not exceed 1.4° C.

(3) *Retest.* If the lot fails to meet the test requirements prescribed in paragraph (b)(2) of this section, the test may be repeated once using five other rabbits. The temperature rises recorded for all eight rabbits used in testing shall be included in determining whether the requirements are met. The lot meets the requirements for absence of pyrogens if not more than three of the eight rabbits show individual rises in temperature of 0.6° C or more, and if the sum of the eight individual maximum temperature rises does not exceed 3.7° C.

* * * * *

Effective date: This regulation shall be effective September 22, 1976.

(Sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262).)

Dated: September 15, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76-27668 Filed 9-21-76;8:45 am]

Title 22—Foreign Relations

CHAPTER V—U.S. INFORMATION AGENCY

PART 505—PRIVACY ACT POLICIES AND PROCEDURES

Exemptions of Systems of Records

On July 21, 1976, the United States Information Agency published in the FEDERAL REGISTER (41 FR 30029), proposed amendments to 22 CFR Part 505, adding § 505.15 concerning exemptions of systems of records under the Privacy Act. One comment received questioned the justification for the application of the exemption concerning classified material, 5 U.S.C. 552a(k)(1), to the systems of records "USIA–20–Legal Files—IGC." The Agency sustains the exemption because that system of records may contain records or portions of records that are properly classified and required to be kept secret in the interest of national defense and foreign policy. The Agency adopts the amendments with the following corrections and revisions, which are the result of other comments received.

The phrase "and in order for the Agency's security staff to properly perform its functions" in § 505.15(a)(1) is deleted because it is superfluous to the language of the exemption.

Section 505.15(a)(3) concerning exemptions under 5 U.S.C. 552a(k)(4) is deleted. After additional review of this proposal, the Agency has concluded that there is no statutory basis for the proposed exemptions of statistical records in the systems of records mentioned.

The adopted § 505.15 as corrected and revised reads as follows:

§ 505.15 Exemptions of systems of records.

Portions of the following systems of records may be exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4), (G), (H) and (I), and (f).

(a) Exempt under 5 U.S.C. 552a(k)(1). The reason for invoking this exemption is to protect material required to be kept secret in the interest of national defense and foreign policy.

USIA–20—Legal Files—IGC
USIA–25—Personnel Security and Integrity Records—IOS

(b) Exempt under 5 U.S.C. 552a(k)(2). The reasons for invoking this exemption are to prevent individuals who are subjects of an investigation from frustrating the investigatory process; to insure the integrity of law enforcement activities; to prevent the disclosure of investigative techniques; and to protect the confidentiality of sources of information.

USIA–20—Legal Files—IGC
USIA–25—Personnel Security and Integrity Records—IOS

(c) Exempt under 5 U.S.C. 552a(k)(5). The reasons for invoking this exemption are to insure the proper functioning of the investigatory process, to insure effective determination of suitability, eligibility and qualifications for employment, and to protect the confidentiality of sources of information:

USIA–13—Employee Relations File—IPT
USIA–16—Equal Employment Opportunity Complaint File—IEO
USIA–17—Equal Employment Opportunity General Files—IEO
USIA–20—Legal Files—IGC
USIA–25—Personnel Security and Integrity Records—IOS
USIA–31—Recruitment Records—IPT

(d) Exempt under 5 U.S.C. 552a(k)(6). The reasons for invoking this exemption are to prevent the compromise of testing or evaluation material used solely to determine individual qualifications for employment or promotion, and to avoid giving unfair advantage to individuals by virtue of their having access to such material:

USIA–13—Employee Relations File—IPT
USIA–14—Employee Training File—IPT
USIA–22—Master Employee Records—IPT
USIA–31—Recruitment Records—IPT

Dated: September 15, 1976.

EUGENE P. KOPP,
Deputy Director.

[FR Doc.76–27646 Filed 9–21–76;8:45 am]

Title 38—Pensions, Bonuses, and Veterans' Relief

CHAPTER I—VETERANS ADMINISTRATION

PART 1—GENERAL PROVISIONS

Release of Information From Other Than Claimant Records; Schedule of Fees

On page 32247 of the FEDERAL REGISTER of August 2, 1976 a notice was published that the Veterans Administration was considering amending Part 1, Title 38 of the Code of Federal Regulations to change the schedule of fees indicated in § 1.555(h)(2) pertaining to charges for document search. The proposed amendment was issued to eliminate the minimum search charge for the release of information from other than claimant records and to provide that there will be no charge for the first hour or fraction thereof.

Interested persons were given 30 days in which to submit comments, suggestions, or objections regarding the proposed amendment. No comments were received. The proposed amendment to § 1.555(h)(2) is adopted without change.

Effective date: This amendment is effective September 16, 1976.

Approved: September 16, 1976.

By direction of the Administrator.

A. J. SCHULTZ, Jr.,
Associate Deputy Administrator.

In § 1.555, paragraph (h)(2) is revised to read as follows:

§ 1.555 Fees.

* * * * *

(h) Schedule of fees: * * *

(2) Searching, per hour	$3.50
(No charge for the first hour or fraction thereof)	

* * * * *

[FR Doc.76–27780 Filed 9–21–76;8:45 am]

Title 50—Wildlife

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 32—HUNTING

Crab Orchard National Wildlife Refuge, Ill.

The following special regulation is issued and is effective September 22, 1976.

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

ILLINOIS

CRAB ORCHARD NATIONAL WILDLIFE REFUGE

Public hunting of ducks, coots, and geese on the Crab Orchard National Wildlife Refuge, Illinois is permitted in accordance with the seasons and limits established by the Illinois Department of Conservation. The area open to hunting is designated by green public hunting signs. This open area is delineated on a map available at refuge headquarters, Carterville, Illinois 62918 and from the Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111. Hunting will be in accordance with all applicable State and Federal regulations subject to the following special conditions:

(1) Blinds—the building of permanent blinds of any kind or other structural works on the refuge public hunting area is prohibited. All blinds must be of a portable nature or constructed with dead vegetation located at the blind site and must be removed or dismantled at the end of the day's hunt. Blinds may not be constructed beyond the shoreline on refuge waters.

(2) A blind shall be defined as the artificial or natural materials arranged so as to conceal the hunter.

(3) All blinds located on the following islands will be filled by public drawing prior to each day's hunt. Grassy Island, Turkey Island, Sawmill Island and Orchard Island. This drawing will be conducted at 5:00 a.m. each day of goose season. No blinds may be constructed on these islands. Only the blinds furnished and located by the refuge staff may be used.

(4) No goose pits may be built on the refuge public hunting area.

(5) It is unlawful for any person to establish or use any blind for the taking of migratory waterfowl within 100 yards of any other blind on the refuge public hunting area.

(6) All persons hunting geese on the refuge public hunting area must register before entering and upon leaving the area and must register any geese taken on the area at the locations designated by the Project Manager.

(7) Hunting will not be permitted at the Carterville Beach area as posted by the Project Manager.

(8) All goose hunting at the Grassy Point and Carterville public area shall be subject to the following special conditions:

a. All blinds will be allotted by a daily drawing conducted at the Carterville hunting area.

b. Hunting will be allowed only from the existing blinds as established by the Project Manager.

c. Drawing will take place at 5:30 a.m. daily.

d. All applicants must be present for drawing.

e. Each hunter is permitted a maximum of 20 shells.

f. Shooting hours will be from Sunrise to 12 Noon daily.

g. Two hunters per blind will be allowed.

h. For the use of established blinds and decoys there will be a $2 charge per hunter.

i. No alcoholic beverages are permitted in the hunting area.