be entitled to submit in writing any other information that it desires to make available to the Commission before it shall act. The Executive Director may require documents to be certified or otherwise authenticated and statements to be verified. The Commission may also receive written submissions from any other persons as to whether a violation has occurred and the adverse consequences resulting from a violation of the Commission's Compact or its rules, regulations and orders.

(b) *Presentation to the Commission.* At the date set in the Notice, the possible violator shall have the opportunity to supplement its written presentation before the Commission by any oral statement it wishes to present and shall be prepared to respond to any questions from the Commission or its staff or to the statements submitted by persons affected by the possible violation.

§ 401.94 Adjudicatory hearings.

(a) An adjudicatory hearing, which may be in lieu of or in addition to proceedings pursuant to § 401.93 at which testimony may be presented and documents received shall not be scheduled unless:

(1) The Executive Director determines that a hearing is required to have an adequate record for the Commission; or

(2) The Commission directs that such a hearing be held.

(b) If an adjudicatory hearing is scheduled, the possible violator shall be given at least 14 days written notice of the hearing date unless waived by consent. Notice of such a hearing may be given to the general public and the press in the manner provided in Section 14.4(b) of the Compact but may be waived by the Executive Director.

(c) Except to the extent inconsistent with the provisions of this Subpart adjudicatory hearings shall be conducted in accordance with the provisions of §§ 491.83 through 401.88 (including § 401.86 *et seq.*).

§ 401.95 Assessment of a penalty.

The Executive Director may recommend to the Commission the amount of the penalty to be imposed. Such a recommendation shall be in writing and shall set forth the basis for the penalty amount proposed. Based upon the record submitted to the Commission, the Commission shall decide whether a violation has occurred that justifies the imposition of a penalty pursuant to § 14.17 of the Compact. If it is found that such a violation has occurred, the Commission shall determine the amount of the penalty to be paid.

§ 401.96 Factors to be applied in fixing penalty amount.

(a) Consideration shall be given to the following factors in deciding the amount of any penalty or any settlement in lieu of penalty:

(1) Previous violation, if any, of the Commission's Compact and regulations;

(2) Whether the violation was unintentional or willful and deliberate;

(3) Whether the violation caused adverse environmental consequences and the extent of any harm;

(4) The costs incurred by the Commission or any signatory party relating to the failure to comply with the Commission's Compact and regulations;

(5) The extent to which the violator has cooperated with the Commission in correcting the violation and remediating any adverse consequences or harm that resulted therefrom; and

(6) Whether the failure to comply with the Commission's Compact and regulations was economically beneficial to the violator.

(b) The Commission retains the right to waive any penalty or reduce the amount of the penalty should it determine that, after consideration of the factors in paragraph (a) of this section, extenuating circumstances justify such action.

§ 401.97 Enforcement of penalties.

Any penalty imposed by the Commission shall be paid within 30 days or such further time period as shall be fixed by the Commission. The Executive Director and Commission counsel are authorized to take such action as may be necessary to assure enforcement of this Subpart. If a proceeding before a court becomes necessary, the action of the Commission in determining a penalty amount shall constitute the penalty amount recommended by the Commission to be fixed by the court pursuant to § 14.17 of the Compact.

§ 401.98 Settlement by agreement in lieu of penalty.

A possible violator may request settlement of a penalty proceeding by agreement. If the Executive Director determines that settlement by agreement in lieu of a penalty is in the best interest of the Commission, he may submit to the Commission a proposed settlement agreement in lieu of a penalty. No settlement will be considered by the Commission unless the possible violator has indicated to the Commission acceptance of the terms of the agreement and the intention to comply with all requirements of the settlement agreement including payment of any settlement amount within the time period provided. If the Commission determines not to approve a settlement agreement, the Commission may proceed with a penalty action in accordance with this Subpart.

§ 401.99 Suspension or modification of penalty.

The Commission may postpone the imposition of a penalty or provide for reconsideration of the penalty amount imposed pending correction of the condition that gave rise to the violation or pending a satisfactory resolution of any adverse consequences that resulted from the violation.

(Delaware River Basin Compact, 75 Stat. 688)

Susan M. Weisman,

Secretary, September 28, 1987.

[FR Doc. 87-22893 Filed 10-7-87; 8:45 am]

BILLING CODE 6360-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

Application of Dependency Test to Adopted Great-Grandchildren and Demonstration Projects Under the Disability Insurance and Supplemental Security Income Programs

AGENCY: Social Security Administration, HHS.

ACTION: Final rules.

SUMMARY: The Social Security Administration (SSA) is amending its regulations to implement sections 12101 and 12104 of Pub. L. 99-272 (the Consolidated Omnibus Budget Reconciliation Act of 1985). Section 12101 of Pub. L. 99-272 extends the Secretary's waiver authority on demonstration projects in the title II disability insurance program which was originally provided for by section 505(a)(3) of the Social Security Disability Amendments of 1980 (Pub. L. 96-265). Section 12101 also effectively makes the waiver authority for title XVI demonstration projects permanent. Section 12104 of Pub. L. 99-272 amends section 202(d)(8)(D)(ii)(III) of the Social Security Act (the Act) to provide that great-grandchildren of a Social Security beneficiary or his or her spouse may be entitled to child's insurance benefits as grandchildren currently are, applying the dependency test for legally adopted children.

DATES: These regulations are effective October 8, 1987. The statutory change regarding great-grandchildren which

these regulations reflect is effective with respect to benefits for which applications for child's insurance benefits are filed April 8, 1986 or later. We will consider any comments concerning these rules that we receive on or before December 7, 1987 and will revise such rules if public comments warrant.

ADDRESSES: Send your written comments to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21203, or deliver them to the Office of Regulations, Social Security Administration, 3–B–4 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235 between 8:00 a.m. and 4:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Henry D. Lerner, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (301) 594–7463.

SUPPLEMENTARY INFORMATION: We published final regulations covering the rules on demonstration projects in the disability insurance and Supplemental Security Income (SSI) programs on February 23, 1983 (48 FR 7573). The rules implemented section 505 of the Social Security Disability Amendments of 1980 (Pub. L. 96–265). Section 505 directed the Secretary of Health and Human Services to develop and carry out experiments and demonstration projects to test the advantages of various ways to facilitate and encourage the return to employment of individuals who would otherwise remain dependent on disability benefits. A key element in conducting these demonstration projects is the authority for the Secretary to waive requirements of the Act related to the subject matter of the projects. A provision of the 1980 amendments calling for a final report within 5 years of the enactment of that statute (no later than June 9, 1985) was interpreted as terminating the Secretary's authority to initiate projects for which such waivers could be made. Without this waiver authority the Secretary was unable to carry out demonstration projects that had not been implemented when the authority expired.

Section 12101 of Pub. L. 99–272 amends section 505(a)(3) of Pub. L. 96–265 by extending the Secretary's waiver authority for 5 years. The deadline for a final report on the disability insurance projects is extended to June 9, 1990. This requirement is made applicable only to the disability program under title II of the Act (section 505(a) of Pub. L. 96–265). Section 12101 effectively grants a permanent extension of the authority to waive the SSI program rules under title XVI which had been provided by section 505(b) of Pub. L. 96–265.

Section 12104 of Pub. L. 99–272 amends section 202(d)(8)(D)(ii)(III) of the Act to provide that great-grandchildren of a Social Security beneficiary or the beneficiary's spouse may be entitled to child's insurance benefits, as grandchildren currently are, applying the dependency test for legally adopted children. Effective for applications filed on April 8, 1986, or later, a great-grandchild may be entitled to benefits if the child is adopted by and lives with the great-grandparent in the United States for at least 1 year before applying for benefits and received at least one-half of his or her support from the beneficiary for at least 1 year; if the child is born within this 1-year period the child must have lived with the beneficiary and received at least one-half of his or her support from the beneficiary for substantially all of the period that begins on the date of the child's birth.

Justification for Final Rules

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act (APA) Notice of Proposed Rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(B), good cause exists for waiver of Notice of Proposed Rulemaking and public comment procedures on this regulation since opportunity for public comment is unnecessary in this case because the statutory provisions upon which the regulations are based simply extend the Secretary's waiver authority on demonstration projects and entitlement to child's insurance benefits to certain great-grandchildren of Social Security beneficiaries. The title II and XVI provisions on demonstration projects and the title II great-grandchildren provisions reflect the statute, are technical in nature and do not provide additional implementing rules. Therefore, these rules will become effective on the date they are published in the **Federal Register.**

Executive Order 12291

The Secretary has determined that these are not major rules under Executive Order 12291 because these regulations do not meet any of the threshold criteria for a major rule. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because these rules affect only individuals and States. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These regulations impose no additional reporting or recordkeeping requirements requiring Office of Management and Budget clearance.

(Catalog of Federal Domestic Assistance Program No. 13802, Social Security—Disability Insurance, 13.803 Social Security—Retirement Insurance, 13.805 Social Security—Survivors Insurance; No. 13807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income.

Dated: February 27, 1987.

Dorcas R. Hardy,

Commissioner of Social Security.

Approved: April 9, 1987.

Otis R. Bowen,

Secretary of Health and Human Services.

Subparts D and P of Part 404 of Chapter III of Title 20 of the Code of Federal Regulations are amended as follows:

PART 404—[AMENDED]

1. The authority citation for Subpart D of Part 404 continues to read as follows:

Authority: Secs. 202, 203 (a) and (b), 205(a), 216, 223, 228(a)–(e), and 1102 of the Social Security Act; 42 U.S.C. 402, 403 (a) and (b), 405(a), 416, 423, 428(a)–(e), and 1302.

§ 404.362 [Amended]

2. In § 404.362, paragraph (b)(2) is amended by inserting "or great-grandchild" after "grandchild" in the title and introductory sentence.

3. The authority citation for Subpart P of Part 404 continues to read as follows:

Authority: Secs. 202, 205 (a), (b), and (d)–(h), 216(i), 221 (a) and (i), 222(c), 223, 225 and 1102 of the Social Security Act; 42 U.S.C. 402, 405 (a), (b), and (d)–(h), 416(i), 421 (a) and (i), 422(c), 423, 425 and 1302; sec. 505(a) of Pub. L. 96–265, 94 Stat. 473; secs. 2(d)(2), (5), (6), and (15) of Pub. L. 98–460, 98 Stat. 1797, 1801, 1802, and 1808.

§ 404.1599 [Amended]

4. In § 404.1599, the third sentence of paragraph (e) is amended by removing "1985" and adding "1990".

Subpart B of Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

5. The authority citation for Subpart B of Part 416 continues to read as follows:

Authority: Secs. 1102, 1110(b), 1602, 1611, 1614, 1615(c), 1619(a), 1631, and 1634 of the Social Security Act; 42 U.S.C. 1302, 1310(b), 1381a, 1382, 1382c, 1382d(c), 1382h(a), 1383, and 1383c; secs. 211 and 212 of Pub. L. 93–66, 87 Stat. 154 and 155; sec. 502(a) of Pub. L. 94–241, 90 Stat. 268; and sec. 2 of Pub. L. 99–643, 100 Stat. 3574.

§ 416.250 [Amended]

6. In § 416.250, paragraph (e) is amended by removing the second and third sentences.

[FR Doc. 87–23296 Filed 10–7–87; 8:45 am]
BILLING CODE 4190–11–M

Food and Drug Administration

21 CFR Part 680

[Docket No. 84N–0349]

Additional Standards for Miscellaneous Products; Allergenic Products; Potency Tests

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the additional standards for allergenic products by adding a reference to the potency test requirement applicable to all biological products under the general biological products standards. The amendment is consistent with the reference in the additional standards for allergenic products to other testing requirements in the general biological regulations, such as identity, safety, and sterility testing. The amendment also provides by regulation for the use of potency testing of allergenic products by methods that measure the allergenic activity of the products. FDA is also removing from its regulations the specific potency test procedure for short ragweed pollen extracts.

DATE: This regulation becomes effective on November 9, 1987.

FOR FURTHER INFORMATION CONTACT: M. Christine Anderson, Center for Drugs and Biologics (HFN–853), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–496–4204.

SUPPLEMENTARY INFORMATION:

I. Background

The additional standards for specific biological products are prescribed under 21 CFR Parts 620 through 680. The additional standards for allergenic products under 21 CFR Part 680 contain specific requirements that supplement the general requirements for all biological products under 21 CFR Part 610 and the current good manufacturing practice requirements under 21 CFR Parts 210 and 211. Sections 610.1 and 610.10 of the general biological regulations require that manufacturers perform a potency test on each lot of licensed biological product before it is released for commercial distribution.

Historically, FDA has permitted manufacturers to label allergenic products with an unstandardized potency level based on a simple weight of allergen to volume of extracting fluid ratio (W/V) or a determination of the protein nitrogen units (PNU) in each lot of manufactured product. Those allergenic products that have potency levels based on W/V or PNU must include the phrase "No U.S. Standard of Potency" on the label. The uncodified procedures for determining W/V or PNU do not result in reliable measures of biological or allergenic activity. FDA believes, consistent with the recommendations of the Panel on Review of Allergenic Extracts (50 FR 3112; January 23, 1985), that these designations should be replaced as soon as practicable by a designation that reflects allergenic activity. FDA recognizes that test methods for measuring the potency of allergenic products are analytical test methods, which may be lengthy, complex, and subject to frequent amendment. See 21 CFR 10.90(b).

Thus far, only extracts of several hymenoptera venoms and short ragweed pollen extracts have been standardized for potency and have had their allergenic activity determined by all manufacturers of the products. In addition, FDA has approved five standardized cat extracts, two species of standardized mite extracts, two standardized extracts of alternaria, and several standardized grass pollen extracts. FDA is reviewing other amendments to manufacturers' license applications for standardized allergenic extracts. Because approximately 1,800 to 2,000 generic allergenic products are marketed, FDA believes that it is impractical to codify a description of each new specific potency test procedure for a product as the procedure is developed, such as the procedure in § 680.4 for short ragweed pollen extract.

In the past, FDA has conducted workshops on standardization to assist manufacturers in the development of potency procedures for their allergenic products (see 45 FR 76251, November 18, 1980; 48 FR 52772, November 22, 1983; and 50 FR 52562, December 24, 1985). Those workshops have included discussion of methods of protein measurements, radial immunodiffusion test, radioallergosorbent tests (RAST), isoelectric focusing, and skin testing. FDA will consider conducting more workshops as needed to assist manufacturers in performing specific potency tests for allergenic products.

II. Proposed Rule

In the **Federal Register** of July 24, 1985 (50 FR 30211), FDA proposed to amend 21 CFR Part 680 concerning the additional standards for allergenic products by adding to § 680.3 *Tests* a new paragraph (e) *Potency*. Section 680.3 already requires that allergenic products meet the general biological testing provisions of 21 CFR Part 610 as those provisions concern identity, safety, and sterility testing. For consistency, § 680.3(e) refers to the general potency requirements under § 610.10. A new § 680.3(f) references the recordkeeping requirements related to the tests performed under § 680.3.

Under new § 680.3(e), the test methods used to measure the potency of allergenic products are required to measure the allergenic activity of the product. FDA will recommend potency test methods to manufacturers when FDA believes that the method results in a reliable measure of biologic or allergenic activity. To facilitate the transition from W/V or PNU to a potency method that measures allergenic activity, FDA will recommend a specific potency test method only after the method has been shown to be effective and has been discussed or demonstrated in one or more public workshops, has appeared in scientific publications, or has been discussed with individual manufacturers. The Director, Office of Biologics Research and Review, Center for Drugs and Biologics, will notify each affected manufacturer in writing of the recommended procedure. This notification will allow a reasonable

time period for manufacturers to begin potency testing based on the recommended procedure or another potency test method that also results in a reliable measure of the potency of the product. Manufacturers will be required to submit amendments to the product license application and to obtain FDA's approval of the amendments, including appropriate potency labeling and lot release requirements. On or after the date established by FDA for implementation of a potency test method that reflects allergenic activity, the agency will consider new lots of that product that are introduced initially into interstate commerce by the licensee to be safe and effective and not misbranded only if the product's potency has been measured under FDA approved procedures. The agency intends to initiate license revocation proceedings or other enforcement actions for any such product for which the potency is not measured in terms of allergenic activity.

As discussed above, when FDA recommends a potency test method for an allergenic product, each licensed manufacturer must submit to FDA and receive approval from FDA within a specified time period appropriate amendments to its license application showing that the recommended method (or an approved alternative method) is used and that labeling is revised if necessary. FDA analytical methods are available for public disclosure under 21 CFR Part 20 (see 21 CFR 10.90(b)(10)).

III. Antigen E Requirements

Section 680.4 has required the standardization of short ragweed pollen extracts based on a determination of the quantity of the major allergen (antigen E) that is present in each lot of the product. The method for performing antigen E testing is included in each manufacturer's license application. Section 680.4 has been the only codified requirement for a specific standardized potency test for an allergenic product. Because FDA is publishing new § 680.3(e) and (f), FDA is removing § 680.4 *Short ragweed pollen extracts.* This codified requirement for one product is unnecessary, because the antigen E requirement for short ragweed pollen extracts is replaced by the requirements in new § 680.3(e).

FDA is making available its recommended test procedures for short ragweed pollen extracts as authorized in 21 CFR 10.90(b)(10) of its administrative practices and procedures regulations. The recommended test procedures are described in a document entitled "Recommended Methods for Short Ragweed Pollen Extracts," Docket No. 84S–0344, available for public examination at the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. FDA also advises that short ragweed pollen extracts, or any mixed product containing short ragweed pollen extract as a component, continue to be subject to the antigen E method, as set forth in the license applications. The antigen E method is FDA's recommended test method for short ragweed pollen extracts.

IV. Comments

In response to the published proposal of July 24, 1985 (50 FR 30211), FDA received two letters of comment. The comments opposed the proposed rule on the basis that any required new standardized test methods that are not codified as step-by-step procedures may not benefit sufficiently from inputs of the industry, health professionals, scientific societies, researchers, and the general public. One of the comments stated that the promulgation of new specific potency test procedures falls within the scope of the rulemaking provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and the Administrative Procedure Act (5 U.S.C. 553). One of the comments said that the proposed standardization process could result in a substantial economic and administrative impact on manufacturers. The comments recommended, therefore, that FDA continue the antigen E requirements under § 680.4 and that all future individual official potency standards be codified.

FDA believes the comments misconstrued the intent of the rule. As stated in the preamble to the proposed rule and elsewhere in the preamble to this final rule, the agency believes that the traditional units used as an indicator of a product's potency (i.e., PNU and W/V) do not result in reliable measures of biological or allergenic activity and should be replaced by a designation that reflects allergenic activity. FDA recognizes that the comments may have misinterpreted the proposed rule as requiring manufacturers to adopt whatever particular test method the agency recommends for a specific product. The agency is therefore changing the language of § 680.3(e) to clarify that the rule does not require that manufacturers incorporate a specific test method recommended by FDA into the manufacturer's license application. Rather, the intent of the rule is to provide that the potency of allergenic products be measured by test methods that result in reliable measures of the products' potency. Neither comment objected to the measurement of allergenic activity as the means by which the potency of allergenic products is determined.

With regard to manufacturers' concerns that they be involved in the implementation of potency test methods for specific allergenic products, FDA notes that manufacturers will have an opportunity to participate in any workshop conducted by FDA and may submit their views at any time on any potency test method including methods discussed in scientific publications.

FDA will not recommend a test method until the method has been shown to be effective and has been discussed or demonstrated in public workshops, has appeared in scientific publications, or has been discussed with individual manufacturers.

Although the comments suggested that FDA promulgate specific potency test methods that apply to individual allergenic products, the codification of such methods is unnecessary, and could involve methods that are lengthy, complex, and subject to frequent changes so that their codification could interfere with timely amendments by manufacturers to their license applications to incorporate new advances in scientific procedures. FDA recognizes that more than one appropriate measurement of allergenic activity may exist for a specific allergenic product, and this rule provides flexibility so that more than one method may be used provided any methods used results in reliable measurements of a product's potency.

FDA recognizes that for the vast majority of allergenic products potency test methods have not yet been developed. Therefore, an exception has been built into the final rule to allow the continued use of the traditional units applied to allergenic extracts (i.e., PNU or W/V) until a potency test method that measures allergenic activity exists and FDA notifies manufacturers of the existence of such a test method.

FDA disagrees with the comment suggesting that standardization of allergenic extracts could result in a substantial economic impact on manufacturers. This comment was not accompanied by any data to support the comment. In the economic assessment of the final rule for short ragweed pollen extract, FDA concluded that the standardization of short ragweed pollen extract would not result in a significant adverse economic impact and, indeed, would provide an economic benefit to users of the product (see 46 FR 39131, item number 11, July 31, 1981). Since that

time, several manufacturers of other allergenic products have amended their license applications to include potency test methods which result in reliable measures of the allergenic activity of the products. The allergenic extracts which have been standardized by some manufacturers include, but are not limited to, cat extract, mite extract, purified hymenoptera venom extracts, and several pollen extracts, including extracts of orchard, red top, june, rye, and meadow fescue grasses. The well-established methods that are being used or are being considered for use as approved potency test procedures include radial immunodiffusion, isoelectric focusing, RAST inhibition, and for extracts of purified hymenoptera venoms, a hyaluranidase enzyme assay. FDA believes that testing by these potency procedures would result in better products and would not create a significant economic impact on manufacturers.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act

Section 680.3 contains collection of information requirements already submitted to and approved by the Office of Management and Budget (OMB) under section 3507 of the Paperwork Reduction Act of 1980. The requirements of § 680.3 express the requirements of 21 CFR 211.165, 211.167, 211.188, and 211.194 (OMB control number 0910–0139), as those requirements apply to allergenic products tests.

VII. Economic Impact

FDA has examined the regulatory impact and regulatory flexibility implications of the regulation in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). Specifically, the regulation identifies in the additional standards for allergenic products the potency test requirement under § 610.10 and the requirements in various sections in Parts 210 and 211 that apply to all licensed biological products.

The regulation provides for the eventual standardization of allergenic extracts by well-established methods that will measure the quantity of allergenic activity in specific allergenic extracts. About 15 manufacturers of allergenic extracts, approximately half of which are small establishments, will be affected by this rule. As technology for a new method is developed and the method becomes well-established, the new method or another reliable method would replace the weight-to-volume designation of potency or the PNU potency method as the acceptable potency test for a specific product. The costs to a manufacturer for standardizing a lot of a specific allergenic extract when standardization is required will vary from zero to several hundred dollars depending on whether the manufacturer produces that product and, if so, has already standardized the product or is in the process of standardizing it. A limited number of allergenic extracts produced by several manufacturers have already been standardized. The standardization of these allergenic extracts has not resulted in significant changes in manufacturing procedures or in the costs and availability of the products. Indeed, certain standardized allergenic extracts are sold at the same price as the corresponding unstandardized extracts. Therefore, the agency has concluded that any anticipated costs resulting from this rule are insufficient to warrant designation as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291. Further, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

List of Subjects in 21 CFR Part 680

Biologics, Allergenic products.

Therefore, under the Public Health Service Act and under the authority delegated to the Commissioner of Food and Drugs, Part 680 is amended as follows:

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

1. The authority citation for 21 CFR Part 680 continues to read as follows:

Authority: Sec. 215, 351, 58 Stat. 690 as amended, 702 as amended (42 U.S.C. 216, 262); 21 CFR 5.10.

2. In § 680.3 by reserving paragraph (d) and adding new paragraphs (e) and (f) and a parenthetical statement at the end of the section to read as follows:

§ 680.3 Tests.

* * * * *

(d) [Reserved]

(e) *Potency.* The potency of each lot of each Allergenic Product shall be determined as prescribed in § 610.10 of this chapter. Except as provided in this section, the potency test methods shall measure the allergenic activity of the product. Until manufacturers are notified by the Director, Office of Biologics Research and Review, of the existence of a potency test that measures the allergenic activity of an allergenic product, manufacturers may continue to use unstandardized potency designations.

(f) *Records.* The records related to the testing requirements of this section shall be prepared and maintained as required by §§ 211.165, 211.167, 211.188, and 211.194 of this chapter.

(Collection of information requirements in this section were approved by the Office of Management and Budget under OMB control number 0910–0139.)

§ 680.4 [Removed]

3. By removing § 680.4 *Short ragweed pollen extracts.*

Dated: July 27, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–23256 Filed 10–7–87; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 201, 203, and 234

[Docket No. N–87–1738; FR–2111]

Mortgage Insurance; Changes to Maximum Mortgage Limits for Single Family Residences, Condominiums and Manufactured Homes and Lots

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of revisions to FHA maximum mortgage limits for high-cost areas.

SUMMARY: This notice amends the listing of areas eligible for "high-cost" mortgage limits under certain of HUD's insuring authorities under the National Housing Act by (1) revising the mortgage limits for Windham County, Connecticut; (2) adding "high-cost" mortgage limits for Cheshire County, New Hampshire; and (3) increasing the mortgage limits for Allentown-Bethlehem, Pennsylvania, MSA. Mortgage limits are adjusted in the area when the Secretary determines that middle- and moderate-income persons