redesignated paragraphs (b)(7) and (b)(8), and adding a new paragraph (b)(9) to read as follows:

§ 416.1231 Burial spaces and certain funds set aside for burial expenses.

(a) * * *

(1) * * *

(2) *Burial spaces defined.* For purposes of this section "burial spaces" include burial plots, gravesites, crypts, mausoleums, urns, niches, and other customary and traditional repositories for the deceased's bodily remains provided such spaces are owned by the individual or are held for his or her use. Additionally, the term includes necessary and reasonable improvements or additions to or upon such burial spaces including, but not limited to, vaults, headstones, markers, plaques, or burial containers and arrangements for opening and closing the gravesite for burial of the deceased. A burial space can be held for an individual under a contract. We do not consider a burial space "held for" an individual under a contract unless the individual currently owns and is currently entitled to the use of the space under that contract. For example, we will not consider a burial space "held for" an individual under an installment sales contract or other similar device under which the individual does not currently own nor currently have the right to use the space, nor is the seller currently obligated to provide the space, until the purchase amount is paid in full.

* * * * *

(b) *Funds set aside for burial expenses.* (1) *Exclusion.* In determining the resources of an individual (and spouse, if any) there shall be excluded an amount not in excess of $1,500 each of funds specifically set aside for the burial expenses of the individual or the individual's spouse. This exclusion applies only if the funds set aside for burial expenses are kept separate from all other resources not intended for burial of the individual (or spouse) and are clearly designated as set aside for the individual's (or spouse's) burial expenses. If excluded burial funds are mixed with resources not intended for burial, the exclusion will not apply to any portion of the funds. This exclusion is in addition to the burial space exclusion.

* * * * *

(3) *Burial funds defined.* For purposes of this section "burial funds" are revocable burial contracts, burial trusts, other burial arrangements (including amounts paid on installment sales contracts for burial spaces), cash, accounts, or other financial instruments with a definite cash value clearly designated for the individual's (or spouse's, if any) burial expenses and kept separate from nonburial-related assets. Property other than listed in this definition will not be considered "burial funds."

(4) *Recipients currently receiving SSI benefits.* Recipients currently eligible as of July 11, 1990 who have had burial funds excluded which do not meet all of the requirements of paragraphs (b) (1) and (3) of this section must convert or separate such funds to meet these requirements unless there is an impediment to such conversion or separation; i.e., a circumstance beyond an individual's control which makes conversion/separation impossible or impracticable. For so long as such an impediment or circumstance exists, the burial funds will be excluded if the individual remains otherwise continuously eligible for the exclusion.

* * * * *

(7) *Increase in value of burial funds.* Interest earned on excluded burial funds and appreciation in the value of excluded burial arrangements which occur beginning November 1, 1982, or the date of first SSI eligibility, whichever is later, are excluded from resources if left to accumulate and become part of the separate burial fund.

(8) *Burial funds used for some other purpose.* (i) Excluded burial funds must be used solely for that purpose.

(ii) If any excluded funds are used for a purpose other than the burial arrangements of the individual or the individual's spouse for whom the funds were set aside, future SSI benefits of the individual (or the individual and eligible spouse) will be reduced by an amount equal to the amount of excluded burial funds used for another purpose. This penalty for use of excluded burial funds for a purpose other than the burial arrangements of the individual (or spouse) will apply only if, as of the first moment of the month of use, the individual would have had resources in excess of the limit specified in § 416.1205 without application of the exclusion.

(9) *Extension of burial fund exclusion during suspension.* The exclusion of burial funds and accumulated interest and appreciation will continue to apply throughout a period of suspension as described in § 416.1321, so long as the individual's eligibility has not been terminated as described in §§ 416.1331 through 416.1335.

[FR Doc. 90-16145 Filed 7-10-90; 8:45 am]

BILLING CODE 4190-11-M

20 CFR Part 416

RIN 0960-AC65

Exclusion of Certain Housing Assistance Payments From Income and Resources in the Supplemental Security Income Program

AGENCY: Social Security Administration, HHS

ACTION: Final rule.

SUMMARY: This rule implements section 8103 of Public Law 100-647 which amended title XVI of the Social Security Act to provide that, for purposes of determining eligibility or benefit amount under the supplemental security income (SSI) program, the countable income or resources of an individual shall not include assistance paid, with respect to a dwelling unit occupied by such individual, under the United States Housing Act of 1937, the National Housing Act, section 101 of the Housing and Urban Development Act of 1965, title V of the Housing Act of 1949, or section 202(h) of the Housing Act of 1959.

EFFECTIVE DATE: These rules are effective on July 11, 1990.

FOR FURTHER INFORMATION CONTACT: Irving Darrow, Esq., Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (301) 965-1755.

SUPPLEMENTARY INFORMATION: Section 2(h) of Public Law 94-375 (the Housing Authorization Act of 1976) enacted August 3, 1976, provided that the value of any assistance paid with respect to a dwelling unit under the United States Housing Act of 1937, the National Housing Act, section 101 of the Housing and Urban Development Act of 1965, or title V of the Housing Act of 1949, may not be considered as income or a resource for the purpose of determining eligibility or benefit amount under the supplemental security income (SSI) program.

These exclusions are already listed in the appendix to 20 CFR part 416, subpart K, which lists types of income excluded from consideration under the SSI program by Federal laws other than the Social Security Act. These exclusions also are contained in current § 416.1236, which lists exclusions from resources provided by statutes other than the Social Security Act. Section 8103 of Public Law 100-647 (The Technical and Miscellaneous Revenue Act of 1988) enacted November 10, 1988, amended sections 1612(b) and 1613(a) of the Social Security Act (42 U.S.C. 1382a(b)

and 1382b(a), respectively) to include in the Act for the first time the housing assistance exclusions contained in section 2(h) of Public Law 94–375 and to add a housing assistance exclusion from income and resources contained in section 202(h) of the Housing Act of 1959. Section 8103 of Public Law 100–647 included payments under section 202(h) of the Housing Act of 1959 to correct the inadvertent elimination of the income and resource exclusion under section 8 of the 1937 Housing Act when the provision for such housing assistance was placed under section 202 of the Housing Act of 1959.

These housing assistance exclusions are being added to §§ 416.1124(c), 416.1210, and 416.1238 of the regulations as an indication that these exclusions are now provided under the Social Security Act, rather than under statutes other than the Act.

Justification for Dispensing With Rulemaking Procedures

We are publishing these amendments without prior notice and public procedure thereon. 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 regulations. The APA provides exceptions to its notice and comment requirements when an agency finds there is good cause for dispensing with such procedures. Section 553(b)(3)(B) of the APA exempts application of notice and comment rulemaking procedures "when the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." We find good cause to dispense with notice of proposed rulemaking in the case of these rules because we find that such rulemaking is "unnecessary" since we are only reflecting the statutory provisions in the regulations and these provisions do not require any exercise of discretion.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291, since there are no costs associated with the regulation and the threshold criteria for a major rule are not otherwise met. 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 they will affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, 5 U.S.C. 601 through 612, is not required.

Paperwork Reduction Act

These regulations do not impose reporting and recordkeeping requirements necessitating clearance by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental security income (SSI).

Dated: April 18, 1990.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: May 22, 1990.

Louis W. Sullivan,

Secretary of Health and Human Services.

Part 416 of title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

1. The authority citation for subpart K of part 416 continues to read as follows:

Authority: Secs. 1102, 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631, of the Social Security Act; 42 U.S.C. 1302, 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383; sec. 211 of Pub. L. 93–66, 87 Stat. 154; sec. 2639 of Pub. L. 98–369, 98 Stat. 1144.

2. In § 416.1124, the word "and" at the end of paragraph (c) (12) is removed and added to the end of paragraph (c)(13), and a new paragraph (c)(14) is added to read as follows:

§ 416.1124 Unearned income we do not count.

* * * * *

(c) *Other unearned income we do not count.* We do not count as unearned income—* * *

(14) The value of any assistance paid with respect to a dwelling unit under—

(i) The United States Housing Act of 1937;

(ii) The National Housing Act;

(iii) Section 101 of the Housing and Urban Development Act of 1965;

(iv) Title V of the Housing Act of 1949; or

(v) Section 202(h) of the Housing Act of 1959.

3. In § 416.1161, a new paragraph (a)(18) is added to read as follows:

§ 416.1161 Income of an ineligible spouse, ineligible parent, and essential person for deeming purposes.

* * * * *

(a) * * *

(18) Housing assistance as provided in § 416.1124(c)(14).

* * * * *

4. The authority citation for subpart L of part 416 continues to read as follows:

Authority: Secs. 1102, 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631 of the Social Security Act; 42 U.S.C. 1302, 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383; sec. 211 of Pub. L. 93–66, 87 Stat. 154.

5. In § 416.1210, a new paragraph (n) is added to read as follows:

§ 416.1210 Exclusions from resources; general.

* * * * *

(n) Housing assistance as provided in § 416.1238.

§ 416.1236 [Amended]

6. In § 416.1236, paragraph (a)(12) is removed and reserved.

7. Section 416.1238 is added to read as follows:

§ 416.1238 Exclusion of certain housing assistance.

The value of any assistance paid with respect to a dwelling under the statutes listed in § 416.1124(c)(14) is excluded from resources.

[FR Doc. 90–16146 Filed 7–10–90; 8:45 am]

BILLING CODE 4190–11–M

Food and Drug Administration

21 CFR Part 314

[Docket No. 89N–0118]

Technical Revision in the Regulations Governing Drug Master File Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is making minor revisions to the rules governing the submission to FDA of drug master files (DMF's). DMF's are reference files submitted to FDA in support of investigational and marketing applications for human drugs. There are five types of DMF's. This rule revises the titles of the five types to reflect more accurately the purpose of each type of DMF.

EFFECTIVE DATE: August 10, 1990.

FOR FURTHER INFORMATION CONTACT: Adele S. Seifried, Center for Drug

Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 22, 1985 (50 FR 7452 at 7493), FDA adopted new regulations governing the submission and content of DMF's. DMF's are reference files submitted to FDA that are used in the review of investigational and marketing applications for human drugs. DMF's are submitted to the agency to allow another party to reference this material without disclosing to that party the contents of the file. The regulation describes several types of information that may be submitted in a DMF. DMF's are divided into five types according to their contents. In the **Federal Register** of October 17, 1989 (54 FR 42515), FDA proposed minor changes in the titles of the five types of DMF's. In the same issue of the **Federal Register** (54 FR 42569), FDA announced the availability of the final "Guideline for Drug Master Files," which may be consulted for help in preparing and submitting DMF's. The revisions in this final rule are consistent with the guidance provided in that guideline.

This final rule amends 21 CFR 314.420 by revising paragraphs (a)(1), (a)(2), (a)(3), (a)(4), and (a)(5). Type I DMF's, described in 21 CFR 314.420(a)(1), cover the facilities and operating procedures used to manufacture drug products and drug substances. This final rule revises 21 CFR 314.420(a)(1) to make clear that such DMF's are intended to be submitted for foreign but not for domestic manufacturing establishments.

The final rule also revises the title of Type V DMF's from "Preclinical or clinical data" to "FDA-accepted reference information." The change is intended to discourage the submission of Type V DMF's for miscellaneous information, duplicate information, or information that should be included in one of the other types of DMF's.

This final rule also makes minor changes in the regulation to describe more accurately the other three types of DMF's.

II. Summary of Comments and the Agency's Responses

Interested persons were given 60 days to submit written comments on the proposed rule. The agency received five comments. These comments are summarized below with the agency's responses.

FDA proposed to change the title of Type I DMF's from "Facilities and operating procedures used to manufacture a drug substance or drug product" to "Manufacturing site, facilities, operating procedures, and personnel." The proposal also recommended Type I DMF's only for foreign drug manufacturing establishments. Four comments objected to the proposed changes, stating that domestic manufacturers also make use of Type I DMF's to describe information about manufacturing facilities and personnel information that the manufacturers may not wish to disclose to third parties. Several comments suggested that Type I DMF's are useful in conveying information about domestic manufacturing sites when multiple sites are used for manufacture. Several comments contended that the proposed change would compel manufacturers to submit the same information about manufacturing sites in each affected investigational new drug (IND) application or new drug application (NDA). Finally, one comment stated that the proposed change would compel a manufacturer to include DMF-type information for all facilities belonging to its suppliers.

As explained in the preamble to the proposed rule, Type I DMF's are sometimes useful for planning and conducting inspections of foreign establishments but are generally not helpful for domestic establishments because of FDA's generally greater familiarity with the location and layout ofsuch establishments. An FDA on-site inspection of a foreign drug manufacturing facility presents unique problems not presented by an inspection of a domestic manufacturing facility. To help FDA plan efficient inspections of foreign manufacturing facilities, some foreign manufacturers have submitted information about their facilities in DMF's. DMF's provide a convenient means to convey such information.

It should be noted that the kind of information about manufacturing facilities and personnel in Type I DMF's is not required to be submitted in either investigational or marketing applications. Thus the change will not cause manufacturers to submit additional Type I DMF information in applications.

Two comments objected to the proposed title change of Type V DMF's. One comment asked that Type V DMF's continue to be used for clinical/preclinical data for a product that may be marketed or used by several drug companies to reduce the amount of paper submitted to FDA. The second comment concurred with the expansion of data allowable in Type V DMF's, but objected to the restriction that FDA be contacted prior to submission of a Type V DMF.

The change in the title of Type V DMF's from "preclinical or clinical data" to "FDA-accepted reference information" is not intended to preclude the use of Type V DMF's for preclinical or clinical data, when necessary. Rather, the change is intended to reflect the use of Type V DMF's for data and information that do not fall under any of the other DMF types.

While a Type V DMF may be used for preclinical or clinical data, the new procedures do reflect the view that a DMF is not usually the best means for submitting clinical or preclinical data to FDA. For example, as noted in the preamble to the proposed rule, FDA has received clinical data in Type V DMF's that should be a part of an IND or NDA. The DMF staff must be contacted before submission of clinical or preclinical data for a Type V DMF to ensure that the DMF is the appropriate file for such information.

III. Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(a)(9) that this technical revision is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

In accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), the agency has carefully analyzed the economic consequences of this final rule. This final rule is merely a technical revision of an existing rule which will have minor but beneficial economic consequences, and the agency has determined that it is, therefore, not a major rule as defined in Executive Order 12291. Further, the Commissioner certifies that this clarification will not have a significant impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

V. Paperwork Reduction Act

The minor technical changes under this rule relate to information collection requirements already submitted to the Office of Management and Budget (OMB) under section 3507 of the Paperwork Reduction Act of 1980 and previously approved under OMB control number 0910-0001.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business

information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 376).

2. Section 314.420 is amended by revising paragraphs (a)(1), (a)(2), (a)(3), (a)(4), and (a)(5) to read as follows:

§ 314.420 Drug master files.

(a) * * *

(1) Manufacturing site, facilities, operating procedures, and personnel (because an FDA on-site inspection of a foreign drug manufacturing facility presents unique problems of planning and travel not presented by an inspection of a domestic manufacturing facility, this information is only recommended for foreign manufacturing establishments);

(2) Drug substance, drug substance intermediate, and materials used in their preparation, or drug product;

(3) Packaging materials;

(4) Excipient, colorant, flavor, essence, or materials used in their preparation;

(5) FDA-accepted reference information. (A person wishing to submit information and supporting data in a drug master file (DMF) that is not covered by Types I through IV DMF's must first submit a letter of intent to the Drug Master File Staff, Food and Drug Administration, 12420 Parklawn Dr., Rm. 2–14, Rockville, MD 20852. FDA will then contact the person to discuss the proposed submission.)

* * * * *

Dated: June 20, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–16118 Filed 7–10–90; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 610

[Docket No. 89N–0109]

General Biological Products Standards; Test for Residual Moisture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations for residual moisture testing of dried (e.g., lyophilized) biological products. The amendment reflects the availablity of alternative analytical methods acceptable to FDA for such testing, and permits manufacturers to select the most appropriate analytical method on a product-by-product basis. The amendment reflects the fact that appropriate residual moisture limits may vary from product to product and that alternative, acceptable analytical methods may yield different residual moisture results for a given product, due to differences in methodological specificity and sensitivity. The amendment permits the appropriate residual moisture limit not to be exceeded for a given product to be reconciled with the specificity and sensitivity of the analytical method used for testing. Elsewhere in this issue of the Federal Register, FDA is announcing the lability of a residual moisture testing guideline consistent with the amended regulation.

EFFECTIVE DATE: This regulation becomes effective July 11, 1990. A manufacturer of a currently licensed dried biological product may continue to use the analytical method and residual moisture limit specified in the product license application for that product. A manufacturer may instead, if deemed warranted for a given product, submit a request to amend the analytical method and/or residual moisture limit currently specified in the product license application for that product. A manufacturer may begin using an alternative analytical method and/or residual moisture limit, effective immediately upon approval of an amended product license application.

ADDRESSES: Submit written requests to amend current product license applications and written requests for exemptions from residual moisture testing to the Director, Center for Biologics Evaluation and Research (HFB–240), 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ann Reed Gaines, Center for Biologics Evaluation and Research (HFB–130), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–295–8188.

SUPPLEMENTARY INFORMATION:

I. Proposed Rule

The existing regulation, § 610.13(a) (21 CFR 610.13(a)), specifies both the analytical method to be used and the residual moisture limit not to be exceeded in dried (T3e.g.,T1 lyophilized) biological products. In the **Federal Register** of June 29, 1989 (54 FR 27389), FDA proposed to revise paragraph (a) to require that each lot of product meet and not exceed the residual moisture limit that is specified in the product license application and determined by an approved method on file.

This amendment reflects, for given products, the lability of alternative analytical methods, in addition to the gravimetric loss-on-drying method described in the existing regulations, for quantitating residual moisture. FDA is amending 21 CFR 610.13(a) because specification of only one approved analytical method prevents the use of alternative analytical methods unless comparative data were submitted in accordance with § 610.9 Equivalent methods and processes (21 CFR 610.9). These alternative methods offer advantages for certain products that include, but are not restricted to, decreased turnaround time for analysis and decreased product aliquot required for analysis. Use of these alternative methods may be more appropriate for certain products, due to considerations such as the amount of product packaged per container during the manufacturing process and the types of moisture (*e.g.*, bound, surface) contained in the product.

This amendment reflects, for given products, the appropriateness of residual moisture limits other than the 1-percent limit cited in the existing regulations and the fact that different, yet still acceptable, analytical methods may yield different residual moisture results, due to differences in methodological specificity and sensitivity. This amendment accommodates such differences in residual moisture results by allowing the analytical method and the correspondingly appropriate residual moisture limit for a given product to be specified by the manufacturer in the product license application.

FDA further proposed to permit exemptions for residual moisture testing of dried biological products to be granted by the Director, Center for Biologics Evaluation and Research. This amendment serves to eliminate this testing requirement when deemed not necessary for the continued safety, purity, and potency of such products.

II. Comments

FDA provided interested persons 60 days to submit written comments on the proposed rule. FDA received three

letters of comment. All the letters generally supported the proposed amendment to the current regulations.

Two comments on proposed § 610.13(a)(1) suggested that the phrase "* * * and other volatile substances * * *" either be defined in or deleted from the regulation. The comments noted that certain of the analytical methods in the draft guideline are specific for water and do not detect other volatile substances.

FDA agrees with the comments. The intent of the regulation is to address only residual moisture defined as water. Other volatile substances are not considered to be significant constituents of currently licensed dried biological products. Therefore, FDA is deleting the phrase "* * * and other volatile substances * * *." In the future, if FDA determines that any volatile substances other than water are significant constituents of dried biological products, FDA will then consider the appropriate analytical method and appropriate residual volatile substances limit not to be exceeded.

III. Effective Date

This rule becomes effective upon date of publication in the **Federal Register**. A manufacturer of a currently licensed dried biological product may continue to use the analytical method and residual moisture limit specified in the product license application for that product. A manufacturer may instead, if deemed warranted for a given product, submit a request to amend the analytical method and/or residual moisture limit currently specified in the product license application for that product. A manufacturer may begin using an alternative analytical method and/or alternative residual moisture limit effective upon approval of an amended product license application.

Section 10.40(c)(4)(i) (21 CFR 10.40(c)(4)(i)) states that the effective date of a final regulation may not be less than 30 days after the date of publication in the **Federal Register** except for a regulation that grants an exemption or relieves a restriction. FDA has determined that this rule is effective upon publication in the **Federal Register** because § 610.13 satisfies the exceptions provided for by § 10.40(c)(4)(i). First, § 610.13 permits exemptions for residual moisture testing of dried biological products to be granted by the Director, Center for Biologics Evaluation and Research, when deemed not necessary for the continued safety, purity, and potency of the product. Second, § 610.13 relieves a restriction in the existing regulation by permitting manufacturers to specify an alternative analytical method for residual moisture testing and/or an alternative residual moisture limit in the product license application for a given product.

IV. Guideline

In that same issue of the **Federal Register** (June 29, 1989; 54 FR 27389), FDA announced the availability of, and invited public comment on, a draft guideline regarding analytical methods for residual moisture testing. This guideline summarized the technical considerations and applicability of both the approved analytical method cited in the existing regulations and those alternative analytical methods now acceptable to FDA. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the final guideline, based on the draft guideline and revised by FDA to incorporate minor changes suggested by interested parties.

V. Economic, Environmental, and Paperwork Considerations

The agency has examined the economic impact of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as specified in the Regulatory Flexibility Act (Pub. L. 96–354). The final rule increases the flexibility of the testing requirement for residual moisture in biological products. The final rule also permits the Director, Center for Biologics Evaluation and Research, to exempt manufacturers from this testing requirement. Therefore, the agency has determined that the final rule is not a major rule as defined in Executive Order 12291. Further, FDA certifies that the final rule will not have a significant impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

The agency has determined under 21 CFR 25.24(a)(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.

As stated in the June 29, 1989, proposal, § 610.13(a)(2) contains cross-references to 21 CFR 211.188 and 211.194, which contain information collection requirements that were submitted for review and approval to the Director, Office of Management and Budget (OMB), as required by section 3507 of the Paperwork Reduction Act of 1980. Those requirements were approved and assigned OMB control number 0910–0139. Therefore, a parenthetical statement is being added at the end of § 610.13.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361, of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

2. Section 610.13 is amended by revising paragraph (a) and by adding an OMB control number at the end of the section to read as follows:

§ 610.13 Purity.

* * * * *

(a)(1) *Test for residual moisture.* Each lot of dried product shall be tested for residual moisture and shall meet and not exceed established limits as specified by an approved method on file in the product license application. The test for residual moisture may be exempted by the Director, Center for Biologics Evaluation and Research, when deemed not necessary for the continued safety, purity, and potency of the product.

(2) *Records.* Appropriate records for residual moisture under paragraph (a)(1) of this section shall be prepared and maintained as required by the applicable provisions of §§ 211.188 and 211.194 of this chapter.

* * * * *

(Information collection requirements were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0139)

Dated: June 20, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–16116 Filed 7–10–90; 8:45 am]

BILLING CODE 4160–01–M