Issued in Seattle, Washington, on March 16, 1990.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 90-6745 Filed 3-23-90; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 89-ANM-016]

Amendment of Medford Control Zone, Medford, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Medford, Oregon, Control Zone by increasing the size of controlled airspace for the establishment of an instrument approach to the Medford-Jackson County Airport. The additional airspace would segregate aircraft operating under Visual Flight Rules (VFR) conditions from aircraft operating under Instrument Flight Rules (IFR) procedures. The area will be depicted on aeronautical charts to provide a reference for the aviation public.

EFFECTIVE DATE: 0901 U.T.C., May 3, 1990.

FOR FURTHER INFORMATION CONTACT: Jerry Parker, ANM-538, Federal Aviation Administration, Docket No. 89-ANM-016, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168, telephone: (206) 431-2525.

SUPPLEMENTARY INFORMATION:

History

On December 11, 1989, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to provide additional controlled airspace for establishment of a VHF omnidirectional range/distance measuring equipment (VOR/DME) approach to the Medford Jackson County Airport, Oregon. (54 FR 50770)

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.171 of part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6F dated January 2, 1990.

The Rule

This amendment to part 71 of the Federal Aviation Regulations will provide additional controlled airspace for establishment of a visual omnidirectional range/distance measuring equipment (VOR/DME) approach to the Medford-Jackson County Airport, Oregon. The additional airspace would segregate aircraft operating under Visual Flight Rules (VFR) conditions from aircraft operating under Instrument Flight Rules (IFR) procedures. The area would be depicted on appropriate aeronautical charts, thereby enabling pilots to circumnavigate the area.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 71 of the Federal Aviation Regulations (14 CFR, part 71), is amended as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.171 [Amendment]

2. Section 71.171 is amended as follows:

Medford, OR [Amended]

On the second line change coordinates to: "(lat. 42°22'21" N. long. 122°52'17" W.)" On the sixth line after "VORTAC" add—"and within 4.5 miles each side of the Medford VORTAC 164 radial extending from the 5 mile radius zone to 26 miles south of the Medford-Jackson County Airport."

Issued in Seattle, Washington, on March 2, 1990.

Temple H. Johnson, Jr.,

Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 90-6746 Filed 3-23-90; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

RIN 0960-AC31

[Regs. Nos. 4 and 16]

Consideration of Vocational Factors

AGENCY: Social Security Administration, HHS.

ACTION: Final rules.

SUMMARY: These regulations reflect longstanding policies which the Social Security Administration follows in making disability determinations and remove an ambiguity which exists in the present regulations regarding the factors that we consider when we determine that a claimant is not disabled because he or she is able to do his or her past work. These regulations do not reflect a substantive change in policy; they are intended only to clarify the longstanding agency implementation of the provisions of the Social Security Act (the Act) and their legislative history relating to disability determinations.

DATES: These rules are effective March 26, 1990.

FOR FURTHER INFORMATION CONTACT: William J. Ziegler, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, telephone (301) 965-1759.

SUPPLEMENTARY INFORMATION: Sections 223(d)(2)(A) and 1614(a)(3)(B) of the Act provide that an individual shall be determined to be under a disability "* * * only if his * * * impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy * * *." This statutory language contemplates consideration of a claimant's vocational factors of age, education, and work experience only in connection with the inquiry into the claimant's ability to do other work, not the kind of work done in the past.

In adjudicating a claim for benefits based on disability, we use a five-step sequential evaluation process set out at §§ 404.1520 and 416.920. At step four of this process, if we have not allowed or denied the claim under one of the first three steps, we determine whether the claimant is able to do any relevant work he or she did in the past. If the claimant can do relevant work he or she did in the past, the claimant is not disabled. If he or she cannot do that past relevant work, we must then decide at the fifth and final step whether, considering the claimant's age, education, and work experience, the claimant can perform other work which exists in the national economy.

In various sections throughout 20 CFR part 404, subpart P, including appendix 2 to that subpart, and part 416, subpart I, and in Social Security Rulings our policy is consistently stated that we consider the vocational factors of age, education, and work experience only in determining whether a claimant is capable of doing any work other than that which he or she did in the past.

Although sections 223(d)(2)(A) and 1614(a)(3)(B) of the Act, and the regulations we have promulgated to reflect these provisions, contemplate consideration of the vocational factors only in connection with the inquiry we make at step five of the sequential evaluation process into the ability of the claimant to do other work, §§ 404.1560 and 416.960 do not state this longstanding interpretation of the statute with sufficient clarity. The existing ambiguity in these regulatory provisions was pointed out in *Velazquez v. Heckler*, 802 F.2d 680 (3d Cir. 1986). To remove this ambiguity, we are amending these two provisions to state, pursuant to our longstanding implementation of these provisions of the Act and their legislative history, that we do not consider the vocational factors of age, education, and work experience in determining whether a claimant is able to do his or her past relevant work.

These changes emphasize at what step in the sequential evaluation process we consider the vocational factors of age, education, and work experience. We are clarifying the current regulations at §§ 404.1560 and 416.960 to emphasize that consideration of whether a person can do past relevant work involves only the comparison of residual functional capacity with the physical and mental demands of that work and does not involve consideration of vocational factors.

Public Comments

We published proposed rules with a notice of proposed rulemaking in the **Federal Register** on June 9, 1988 (53 FR 21685). Interested persons and organizations were given 60 days to comment. The comment period closed on August 8, 1988.

We received comments from four commenters: A State agency that makes disability determinations, an organization representing agencies and professionals that provide rehabilitation services to mentally ill adults, and two attorneys who represent claimants. We have carefully considered all of the substantive comments we received, but, for the reasons explained below, did not adopt any of the recommendations in these comments. However, we made some clarifying changes to paragraph (c) of §§ 404.1560 and 416.960. The changes, which are editorial rather than substantive, do not change the meaning as stated in the proposed regulations.

Comment: The State agency had only one comment. This was a suggestion that we define the term "past relevant work" in the regulations to avoid confusion with the term "work experience," which is defined in existing regulations. One of the attorneys, and the organization which represents rehabilitation service providers for mentally ill adults, stated that past relevant work should refer only to the individual's specific past job, and not the occupation as generally performed in the national economy. Similarly, the two attorneys stated that we should not consider occupations which have undergone technological change, short-term, vaguely remembered occupations, or foreign occupations which do not exist in the national economy as past relevant work.

Response: We use the term "past relevant work" only in connection with the determination as to whether an individual can perform the kind of work he or she did in the past. The term "work experience" refers to the skills and abilities an individual has acquired through work which show the type of work, other than past work, that an individual may be expected to do.

We are examining all the disability regulations to determine the need for restructuring and further clarification. The ongoing examination includes a review of how we consider and define past relevant work, and we will consider these comments in regard to that broader effort. Such consideration exceeds the scope of these final rules which are limited to a clarification of when we consider an individual's age, education, and work experience.

Comment: The two attorneys expressed the view that the clarification is actually a policy change which would remove the vocational factors of age, education, and work experience from the determination of whether an individual can perform his or her past relevant work.

Response: We do not agree With these two comments. As stated in the preamble to the proposed rules, we believe that the statutory language in sections 223(d)(2)(A) and 1614(a)(3)(B) of the Act contemplates consideration of the vocational factors of age, education, and work experience only in connection with the inquiry we make at step five of the sequential evaluation process. At step five we determine an individual's ability to do other work. Applicable sections of the existing regulations which outline the sequential evaluation process, and which we are not changing, are consistent with this view. Sections 404.1520(e) and 416.920(e) state that we review an individual,s residual functional capacity, and the physical and mental demands of his or her past work, to determine whether the impairment(s) prevents the individual from doing past relevant work. Sections 404.1520(f)(1) and 416.920(f)(1), on the other hand, state that we review an individual's residual functional capacity and his or her age, education, and work experience to determine whether the impairment(s) prevents the individual from doing other work. Similarly, section 200.00(a) of Appendix 2 to 20 CFR part 404, subpart P, states that the medical-vocational rules reflect the analysis of the various vocational factors of age, education, and work experience, in combination with the individual's residual functional capacity, in evaluating the individual's ability to engage in substantial gainful activity in other than his or her vocationally relevant past work.

Throughout the history of the disability programs, we have not considered the vocational factors of age, education, and work experience when we determine whether an individual can perform the kind of work he or she did in the past. Therefore, this clarification does not represent a policy change. Rather, it emphasizes what has always been our policy.

Comment: One commenter views the determination of ability to do past relevant work as a purely medical assessment.

Response: In determining the ability to do past relevant work, we compare an individual's residual functional capacity, which is based on objective medical evidence, and any other materinl

evidence, with the physical and mental demands of past relevant work. This evaluation of past relevant work necessarily involves nonmedical considerations.

Comment: The two attorneys stated that we often exclude or understate an impairment's degenerative effects caused by aging in the residual functional capacity assessment.

Response: This is not a matter related to this particular regulatory clarification. It is an apparent adjudicative issue regarding residual functional capacity to be dealt with as appropriate in each individual case.

Comment: One of the attorneys focused on age as a vocational factor, noting our recognition of its possible deteriorative effects and referring to the need to consider it in a highly individualized and flexible manner.

Response: These statements pertain to the consideration of age in determining the ability to do other work which occurs at step five of the sequential evaluation process, not in determining the ability to do past work, which occurs at step four of the sequential evaluation process, so they do not pertain to this regulatory clarification.

Comment: The organization which represents rehabilitation service providers for mentally ill adults stated that mental illness is often episodic and the exclusion of vocational factors has led to inappropriate decisions of not disabled. The organization opposed the exclusion of vocational factors at step four of the sequential evaluation process and urged rejection of the proposed regulations.

Response: The nature of the impairment does not affect the sequential evaluation process. In connection with the inquiry we make at step five of the sequential evaluation process to determine an individual's ability to adjust to other work, we consider the vocational factors of age, education, and work experience for individuals with mental illness or any other impairment. However, regardless of the type of impairment, we do not consider the vocational factors of age, education, and work experience in connection with the inquiry we make at step four of the sequential evaluation process to determine an individual's ability to do past relevant work.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because these regulations do not meet any of the threshold criteria for a major rule. SSA estimates this clarification will have little or no impact on title II or title XVI benefit payments or administrative costs. 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 affect only disability claimants and beneficiaries under title II and title XVI of the Social Security Act. 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 reporting/recordkeeping requirements necessitating clearance by the Office of Management and Budget. All information necessary to make the disability decisions discussed in these regulations is presently collected using forms which have the Office of Management and Budget's clearance.

(Catalog of Federal Domestic Program Nos. 13.802, Social Security Disability Insurance; 13.807, 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: August 23, 1989.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: March 2, 1990.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set out in the preamble, part 404, subpart P, chapter III of title 20, Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE (1950 _____)

Subpart P—Determining Disability and Blindness

20 CFR part 404, subpart P, is amended as follows:

1. The authority citation for subpart P continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d) through (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) through (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.

2. Section 404.1560 is revised to read as follows:

§ 404.1560 When your vocational background will be considered.

(a) *General.* If you are applying for a period of disability, or disability insurance benefits as a disabled worker, or child's insurance benefits based on disability which began before age 22 and we cannot decide whether you are disabled on medical evidence alone, we will consider your residual functional capacity together with your vocational background.

(b) *Past relevant work.* We will first compare your residual functional capacity with the physical and mental demands of the kind of work you have done in the past. If you still have the residual functional capacity to do your past relevant work, we will find that you can still do your past work, and we will determine that you are not disabled, without considering your vocational factors of age, education, and work experience.

(c) *Other work.* If we find that you can no longer do the kind of work you have done in the past, we will then consider your residual functional capacity together with your vocational factors of age, education, and work experience to determine whether you can do other work. By other work we mean jobs that exist in significant numbers in the national economy.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—Determining Disability and Blindness

For the reasons set out in the preamble, part 416, subpart I, chapter III of title 20, Code of Federal Regulations, is amended as set forth below.

1. The authority citation for subpart I is revised to read as follows:

Authority: Secs. 1102, 1614(a), 1619, 1631(a) and (d)(1), and 1633 of the Social Security Act; 42 U.S.C. 1302, 1382c(a), 1382h, 1383 (a) and (d)(1), and 1383b; secs. 2, 5, 6, and 15 of Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808.

2. Section 416.960 is revised to read as follows:

§ 416.960 When your vocational background will be considered.

(a) *General.* If you are age 18 or older and applying for benefits based on

disability and we cannot decide whether you are disabled on medical evidence alone, we will consider your residual functional capacity together with your vocational background.

(b) *Past relevant work.* We will first compare your residual functional capacity with the physical and mental demands of the kind of work you have done in the past. If you still have the residual functional capacity to do your past relevant work, we will find that you can still do your past work, and we will determine that you are not disabled, without considering your vocational factors of age, education, and work experience.

(c) *Other work.* If we find that you can no longer do the kind of work you have done in the past, we will then consider your residual functional capacity together with your vocational factors of age, education, and work experience to determine whether you can do other work. By other work we mean jobs that exist in significant numbers in the national economy.

[FR Doc. 90-6766 Filed 3-23-90; 8:45 am]

BILLING CODE 4190-11-M

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Products Co. Approval of the original NADA limited the feeding of a Type C medicated feed containing monensin to growing turkeys from 1 day of age to 10 weeks of age. The supplemental NADA provides for continuous feeding to growing turkeys.

EFFECTIVE DATE: March 26, 1990.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: Elanco Products Co., a division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 130-736, which provides for use of a Type A medicated article containing 45 grams of monensin per pound to manufacture a Type C medicated feed for growing turkeys. The feed is currently permitted to be fed from 1 day of age to 10 weeks of age and is intended to prevent coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis.* Elanco has filed a supplemental NADA containing data that supports extending use of the medicated feed to growing turkeys that are older than 10 weeks but not mature. The supplement was approved by letter dated March 19, 1990, and 21 CFR 558.355(f)(2)(iii) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary. Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of exclusive marketing privilege from the date of approval.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.355 is amended by revising paragraph (f)(2)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iii) *Limitations.* Feed continuously as the sole ration to growing turkeys from 1 day of age as monensin sodium; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

* * * * *

Dated: March 19, 1990.

Robert C. Livingston,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 90-6754 Filed 3-23-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680

[Docket No. 89N-0082]

Certain Biologics Regulations; Editorial Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its biologics regulations to update the titles and mailing symbols of certain organizational units. This action will improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: March 26, 1990.

FOR FURTHER INFORMATION CONTACT: Rose Marie Wilson, Regulations and Bioresearch Monitoring Staff (HFB-130), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-295-8188.

SUPPLEMENTARY INFORMATION: FDA is amending certain of its biologics regulations in parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680 of title 21 of the Code of Federal Regulations (CFR) to update the titles and mailing symbols of certain organizational units.

Because these amendments are nonsubstantive, notice and public procedure and delayed effective date are unnecessary (5 U.S.C. 553 (b)(B) and (d)).

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 601

Biologics, Confidential business information.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 607

Blood.

21 CFR Part 610

Biologics, labeling, Reporting and recordkeeping requirements.

21 CFR Part 620

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 630

Biologics, Labeling.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 650

Biologics.

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680 and amended as follows:

PARTS 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, 680—[AMENDED]

1. Parts 600, 601, 606, 607, 610, 620, 630, 640, 650, 660, and 680 are amended by removing the words "Office of Biologics Research and Review" and by adding, in their place, the words "Center for Biologics Evaluation and Research" in the following places:

(1) Section 600.11(f)(6);
(2) Section 600.12 (b)(2) and (b)(3);
(3) Section 600.13, everywhere that it appears;
(4) Section 600.15(b);
(5) Section 600.22(e);
(6) Section 601.2(a), everywhere that it appears;
(7) Section 601.3, introductory texts of paragraphs (a) and (b);
(8) Section 601.4(a);
(9) Section 601.6(a)(2);
(10) Section 601.9(a);
(11) Section 601.12 (a) and (b);
(12) Section 601.31;
(13) Section 601.33, everywhere that it appears;
(14) Section 601.51(b);
(15) Section 606.100 (a) and (d)(3);
(16) Section 606.110(b);
(17) Section 607.25(b)(2);
(18) Section 610.2(a), everywhere that it appears;
(19) Section 610.11 (c)(2) and (c)(3);
(20) Section 610.12 (e)(2)(i) and (g)(4)(ii);
(21) Section 610.15(a)(3);
(22) Section 610.18(c)(2);
(23) Section 610.20, introductory text paragraph;
(24) Section 610.40 (a) and (e)(2);
(25) Section 620.6, introductory text of paragraph (h);
(26) Section 620.13(h);
(27) Section 620.14 (c)(2) and (c)(3);
(28) Section 620.21(b);
(29) Section 620.22;
(30) Section 620.24, introductory text of paragraph (c), paragraphs (c)(1) and (c)(3);
(31) Section 620.31(a)(1);
(32) Section 620.32, introductory text paragraph;
(33) Section 620.35, introductory text of paragraph (e), paragraphs (e)(2) and (e)(3);
(34) Section 620.43;
(35) Section 620.44(c), everywhere that it appears;
(36) Section 620.45, introductory text of paragraph (b), paragraphs (b)(1), (b)(4), and (b)(5);
(37) Section 620.48, introductory text of paragraph (a), paragraphs (a)(2) and (b);
(38) Section 630.1 (b) and (c);
(39) Section 630.2(c);
(40) Section 630.3, introductory text paragraph, and paragraph (a);
(41) Section 630.4 (e)(1) and (e)(3);
(42) Section 630.5, introductory text of paragraph (c), and paragraph (c)(4);
(43) Section 630.10 (a), (b)(2), (b)(4), (b)(5), and (b)(6);
(44) Section 630.12 (a)(1) and (b);
(45) Section 630.14;
(46) Section 630.17, introductory text of paragraph (e), and paragraph (e)(1);
(47) Section 630.30(c)(1)(iii);
(48) Section 630.33;
(49) Section 630.36, introductory text of paragraph (h), and paragraph (h)(1)(i);
(50) Section 630.50(c)(1)(ii);
(51) Section 630.53;
(52) Section 630.56, introductory text of paragraph (f), and paragraph (f)(1);
(53) Section 630.60 (d)(3) and (e)(1)(ii);
(54) Section 630.63;
(55) Section 630.66 introductory text of paragraph (e), paragraphs (e)(1)(i) and (e)(3);
(56) Section 630.70(b);
(57) Section 630.72;
(58) Section 630.74(c), everywhere that it appears;
(59) Section 630.75 (d)(1), (d)(1)(i) and (d)(2);
(60) Section 630.81;
(61) Section 630.83;
(62) Section 630.86, introductory text of paragraph (e), paragraphs (e)(1)(i) and (e)(3);
(63) Section 640.2(a);
(64) Section 640.3(a)(1), everywhere that it appears;
(65) Section 640.4(a)(1), everywhere that it appears;
(66) Section 640.6, introductory text paragraph;
(67) Section 640.17;
(68) Section 640.21(c);
(69) Section 640.22(c);
(70) Section 640.25, introductory text of paragraph (c), and paragraph (c)(3);
(71) Section 640.55;
(72) Section 640.56, introductory text of paragraph (c), and paragraph (c)(2);
(73) Section 640.64, introductory text of paragraph (c);
(74) Section 640.66;
(75) Section 640.71(b)(3);
(76) Section 640.73;
(77) Section 640.74 (a) and (b)(2);
(78) Section 640.82(b);
(79) Section 640.92(b);
(80) Section 640.101, introductory text of paragraph (f);
(81) Section 640.104, introductory text of paragraph (c);
(82) Section 640.111, introductory text of paragraph (g);
(83) Section 640.112(b);
(84) Section 650.6, introductory text paragraph, and paragraphs (a) and (c);
(85) Section 650.11, introductory text of paragraph (c), and paragraphs (c)(1) and (c)(5);
(86) Section 660.3;
(87) Section 660.5;
(88) Section 660.6 (a)(2)(iii), (b), (c)(1), (c)(2), everywhere that it appears, and (c)(3);
(89) Section 660.33;
(90) Section 660.34(d);
(91) Section 660.36 (a)(1), (b), and (c);
(92) Section 660.42;
(93) Section 660.44;
(94) Section 660.46 (a)(2)(iii), (b), (c)(1), (c)(2), everywhere that it appears, and (c)(3);
(95) Section 660.101 introductory text;
(96) Section 660.102 (b)(1) and (c)(7);
(97) Section 660.103 (d) and (g)(2)(ii);
(98) Section 660.105, introductory text of paragraph (a), and paragraph (b);
(99) Section 680.3(e);
(100) Section 680.11;
(101) Section 680.12;
(102) Section 680.21;
(103) Section 680.24(e);
(104) Section 680.26, introductory text paragraph, and paragraph (c).

2. Parts 600, 606, and 607 are amended by removing the words "Center for Drugs and Biologics" and by adding, in their place, the words "Center for

Biologics Evaluation and Research" in the following places:

(1) Section 600.10(a);

(2) Section 606.20(a);

(3) Section 606.170(b), everywhere that it appears;

(4) Section 607.22(b).

3. Parts 606, 610, 660, and 680 are amended by removing the words "Office of Biologics Research and Review (HFN–800), Center for Drugs and Biologics" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–1)" in the following places:

(1) Section 606.121(c)(13), introductory text of paragraph (d), and paragraphs (d)(4) and (d)(5);

(2) Section 610.9(b);

(3) Section 610.53(d);

(4) Section 660.53;

(5) Section 660.54 introductory text;

(6) Section 660.55(a)(3);

(7) Section 680.1 (b)(2)(iii), (b)(3)(iv), (c), and (d)(1).

4. Part 607 is amended by removing "§ 312.1" and by adding in its place "Part 312" in the following places:

(1) Section 607.3(e);

(2) Section 607.40(b).

5. Part 607 is amended by removing the words "Office of Compliance, Center for Drugs and Biologics (HFN–315), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–240), 8800 Rockville Pike, Bethesda, MD 20892" in the following places:

(1) Section 607.7 (b) and (c);

(2) Section 607.22(a).

6. Part 660 is amended by removing the words "Office of Biologics Research and Review" and "(HFN–800)" and by adding, in their place, the words "Center for Biologics Evaluation and Research" and "(HFB–1)", respectively, in the following places:

(1) Section 660.6, introductory text of paragraph (a)(2), everywhere that it appears;

(2) Section 660.46, introductory text of paragraph (a)(2), everywhere that it appears.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

7. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

8. Section 600.3 is amended by revising paragraph (d) to read as follows:

§ 600.3 Definitions.

* * * * *

(d) "Center for Biologics Evaluation and Research" means Center for Biologics Evaluation and Research of the Food and Drug Administration.

* * * * *

§ 600.14 [Amended]

9. Section 600.14 *Reporting of errors* is amended in paragraph (a) by removing the words "Center for Drugs and Biologics (HFN–355), 5600 Fishers Lane, Rockville, MD 20857" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–100), 8800 Rockville Pike, Bethesda, MD 20892".

PART 601—LICENSING

10. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 513–516, 518–520, 701, 704, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 376, 381); secs. 215, 301, 351, 352 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263); secs. 2–12 of the Fair Packaging and Labeling Act (5 U.S.C. 1451–1461).

11. Section 601.2 is amended in paragraph (b) by revising the first sentence to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

* * * * *

(b) * * * In lieu of submitting an establishment and product license for the manufacture of a radioactive biological product, as defined in § 600.3(ee) of this chapter, the manufacturer of such a product shall submit a new drug application to the Director, Division of Medical Imaging, Surgical, and Dental Products (HFD–160), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, consistent with the procedures set forth in § 314.50 of this chapter. * * *

§ 601.21 [Amended]

12. Section 601.21 *Products under development* is amended by removing "(21 CFR 312.1)" and replacing it with "(21 CFR part 312)".

§ 601.25 [Amended]

13. Section 601.25 is amended in paragraph (b)(2) by removing the words "office of the Hearing Clerk" and by adding, in their place, the words "Dockets Management Branch".

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

14. The authority citation for 21 CFR part 607 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374); secs. 215, 351 of the Public Health Service Act (42 U.S.C. 216, 262).

§ 607.37 [Amended]

15. Section 607.37 *Inspection of establishment registrations and blood product listings* is amended in the introductory text of paragraph (a) and in paragraph (b) by removing the words "Center for Drugs and Biologics (HFN–315), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–100), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

16. 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).

§ 610.2 [Amended]

17. Section 610.2 *Requests for samples and protocols; official release* is amended in paragraph (b) by removing the words "Office of Drug Research and Review" and by adding, in their place, the words "Center for Drug Evaluation and Research", everywhere that they appear.

§ 610.40 [Amended]

18. Section 610.40 *Test for hepatitis B surface antigen* is amended in paragraph (b)(4) by removing the words "Office of Biologics Research and Review" and "(HFN–800), Center for Drugs and Biologics" and by adding, in their place, the words "Center for Biologics Evaluation and Research", and "(HFB–1)", respectively, and in paragraphs (d)(1)(v) and (d)(2)(iv) by removing the words "Office of Biologics Research and Review (HFN–800)", and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–1)".

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

19. The authority citation for 21 CFR part 620 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).

§ 620.12 [Amended]

20. Section 620.12 *U.S. Standard preparations* is amended in the introductory text paragraph by removing the words "Office of Biologics Research and Review (HFN–890), Center for Drugs and Biologics" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–210)".

§ 620.14 [Amended]

21. Section 620.14 *General requirements* is amended in the introductory text of paragraph (c) by removing the words "Office of Biologics Research and Review (HFN–890), Center for Drugs and Biologics" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–1)".

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

22. The authority citation for 21 CFR part 660 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).

§ 660.36 [Amended]

23. Section 660.36 *Samples and protocols* is amended in the introductory text of paragraph (a) by removing the words "Office of Biologics Research and Review Sample Custodian (ATTN: HFN–895)" and by adding, in their place, the words "Office of Biological Product Review Sample Custodian (ATTN: HFB–215)".

§ 660.52 [Amended]

24. Section 660.52 *Reference preparations* is amended by removing the words "Center for Drugs and Biologics (HFN–890)" and by adding, in their place, the words "Center for Biologics Evaluation and Research (HFB–221)".

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

25. The authority citation for 21 CFR part 680 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).

26. Section 680.11 is amended by revising the section heading to read as follows:

§ 680.11 Pretesting by Center; sample of each lot.

* * * * *

Dated: March 19, 1990.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–6753 Filed 3–23–90; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–3749–1]

Idaho; Final and Interim Authorization of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of final determination on Idaho's application for final and interim authorization.

SUMMARY: Idaho has applied for final authorization of its hazardous waste program under the Resource Conservation and Recovery Act (RCRA) including a request for interim authorization for the corrective action provisions of the Hazardous and Solid Waste Amendments of 1984 (HSWA). The Environmental Protection Agency (EPA) has reviewed Idaho's application and made the determination that Idaho's hazardous waste program satisfies all of the requirements necessary to qualify for final and interim authorization. Thus, EPA is granting final and interim authorization to Idaho to operate its program, subject to the authority retained by EPA in accordance with the Hazardous and Solid Waste Amendments of 1984.

EFFECTIVE DATE: Final and interim authorization for Idaho shall be effective at 1 p.m. on April 9, 1990.

FOR FURTHER INFORMATION CONTACT: Nina Kocourek, Waste Management Branch, HW–112, U.S. EPA, Region 10, 1200 Sixth Avenue, Seattle, Washington 98101, (206) 442–6502.

SUPPLEMENTARY INFORMATION:

A. Background

Section 3006 of the Resource Conservation and Recovery Act (RCRA) allows the Environmental Protection Agency (EPA) to authorize State hazardous waste programs to operate in the State in lieu of the Federal hazardous waste program. To qualify for final authorization, a State's program must (1) Be "equivalent" to the Federal program, (2) be consistent with the Federal program and other State programs, and (3) provide for adequate enforcement (section 3006(b) of RCRA, 42 U.S.C. 6926(b)). States applying for authorization must demonstrate a program equivalent to the Federal program in effect one year prior to the date the application is submitted.

Interim authorization is a temporary authorization which a State can request and which is granted if the evidence submitted shows State requirements are at least substantially equivalent to the Federal program requirement. See section 3006(g)(2), 42 U.S.C. 6926(g)(2). All interim authorizations pursuant to section 3006(g)(2) expire on January 1, 1993. Responsibility for that portion of the program reverts to EPA on that date if a State has not received final authorization for those provisions.

On July 7, 1988, Idaho submitted an official application for final authorization for those non-HSWA and HSWA requirements promulgated as of July 7, 1987. On November 17, 1989, the State requested interim authorization for the HSWA corrective action provisions of section 3004(u), promulgated as of July 7, 1987. The State has incorporated by reference all Federal Regulations in 40 CFR parts 124, 260–266, 268, and 270 that were promulgated and codified as of July 1, 1987. (No changes were made to the Federal RCRA program between July 1, 1987 and July 8, 1987.)

The State's application included aspects of the Land Disposal restrictions Rule (LDR) "California List", (52 FR 25760), promulgated on July 8, 1987. However, at this time these rules are not included in our final authorization decision. These rules will be addressed in a forthcoming program revision action which will give the public an opportunity to review and comment.

During EPA's review of Idaho's application a question arose concerning the scope of Idaho's regulatory exclusion for farmers. EPA excludes from all hazardous waste regulation "farmers" who dispose of waste pesticides from their own use, provided that the disposal meets specified standards. See 40 CFR 264.1(g)(4). Idaho's exclusion specifies that both