or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (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, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority since it contains aircraft executing instrument approach procedures to Tri-City Airport.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE KS E5 Parsons, KS

Parsons, Tri-City Airport, KS
(Lat. 37°19′48″ N., long. 95°30′22″ W.)
Parsons NDB
(Lat. 37°20′17″ N., long. 95°30′31″ W.)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of Tri-City Airport and within 2.5 miles each side of the 009° bearing from the Parsons NDB extending from the 7.5-mile radius of the airport to 7 miles north of the NDB.

* * * * *

Issued in Kansas City, MO, on March 14, 2005.

Anthony D. Roetzel,

Acting Area Director, Western Flight Services Operations.

[FR Doc. 05–5837 Filed 3–23–05; 8:45 am]

BILLING CODE 4910–13–M

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 422

[Regulation Nos. 4 and 22]

RIN 0960–AG24

Technical Amendments To Change a Cross-Reference and To Remove Reference to an Obsolete Form

AGENCY: Social Security Administration.

ACTION: Correcting amendments.

SUMMARY: This document contains two technical corrections to our regulations. The first correction changes a cross-reference in our regulations regarding how we credit quarters of coverage for calendar years before 1978. The second correction removes reference to a form that has been obsolete since November 2002.

EFFECTIVE DATE: Effective on March 24, 2005.

FOR FURTHER INFORMATION CONTACT: Rosemarie Greenwald, Policy Analyst, Office of Program Development and Research, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401. Call (410) 965–5651 or TTY 1–800–325–0778 for information about these correcting amendments. For information on eligibility or filing for benefits, call our national toll-free number 1–(800) 772–1213 or TTY 1–(800) 325–0778. You may also contact Social Security Online at *http://www.socialsecurity.gov/.*

SUPPLEMENTARY INFORMATION: We are making two corrections to our current regulations. The first correction is being made to 20 CFR 404.141, *How we credit quarters of coverage for calendar years before 1978.* The cross-reference in paragraph (d)(1) of this section incorrectly cross-refers to § 404.1027(a). The correct cross reference should be to §§ 404.1047 and 404.1096, which contain the annual wage limitations based on wages and self-employment income.

The second correction we are making is to remove from § 422.505(b) the reference to, and description of, form SSA–1388, Report of Student Beneficiary at End of School Year. This form became obsolete on November 1, 2002.

(Catalog of Federal Domestic Assistance Programs Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 422

Administrative practice and procedure, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Social Security.

Dated: March 17, 2005.

Martin Sussman,

Regulations Officer.

■ For the reasons set out in the preamble, part 404 and part 422 of chapter III of title 20 of the Code of Federal Regulations are corrected by making the following correcting amendments:

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

Subpart B—[Amended]

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

Authority: Secs. 205(a), 212, 213, 214, 216, 217, 223 and 702(a)(5) of the Social Security Act (42 U.S.C. 405 (a), 412, 413, 414, 416, 417, 423 and 902(a)(5)).

§ 404.141 [Amended]

■ 2. Paragraph (d)(1) of § 404.141 is amended by correcting the reference ''§ 404.1027(a)'' to read ''§§ 404.1047 and 404.1096.''

PART 422—ORGANIZATION AND PROCEDURES

Subpart F—[Amended]

■ 3. The authority citation for subpart F continues to read as follows:

Authority: Secs. 205 and 702(a)(5) of the Social Security Act (42 U.S.C. 405 and 902(a)(5).

§ 422.505 [Amended]

■ 4. In the list of forms in paragraph (b) of § 422.505, remove the form SSA—1388 and its description.

[FR Doc. 05–5774 Filed 3–23–05; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 25, 26, 99, 201, 203, 206, 310, 312, 314, 600, 601, 606, 607, 610, 640, 660, 680, 807, and 822

Food and Drug Administration Regulations; Drug and Biological Product Consolidation; Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations regarding biological products to include references to the Center for Drug Evaluation and Research (CDER) or the Director, CDER, and to include CDER address information or updated CDER address information, where appropriate. FDA is also amending the regulations to update mailing address information including mailing codes for the Center for Biologics Evaluation and Research (CBER), and to place the current mailing addresses for certain biologics regulations in a single location. These changes, among others, are being taken to reflect the reorganization between CBER and CDER due to the transfer of responsibility for certain products from CBER to CDER, and to ensure the consistency and accuracy of the regulations.

DATES: This rule is effective March 24, 2005.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. Transfer of Regulatory Responsibility from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research

In a letter dated June 20, 2003, FDA notified sponsors that the regulatory responsibility, review, and continuing oversight for many biological products would be transferred from CBER to CDER. This change in regulatory responsibility resulted in the transfer of applications for the affected product classes (see section I.B of this document). This consolidation initiative was undertaken to provide greater opportunities to further develop and coordinate scientific and regulatory activities between CBER and CDER, leading to a more efficient, effective, and consistent review program for human drugs and biologics.

In the **Federal Register** of June 26, 2003 (68 FR 38067), we published a notice announcing the transfer of certain product oversight from CBER to CDER. On June 30, 2003, the responsibility for regulating most therapeutic biologics, with certain exceptions (e.g., cell and gene therapy products and therapeutic vaccines) was transferred from the Office of Therapeutics Research and Review (OTRR), CBER, to the Office of New Drugs (OND) and the Office of Pharmaceutical Science (OPS), CDER. Initially, this transfer of products was effected when the divisions of OTRR formerly within CBER were detailed to offices within CDER. On October 1, 2003, those CBER offices detailed to CDER were incorporated into CDER's organizational structure. Throughout these transitions, the staff that was formerly with OTRR, CBER, maintained responsibility for the therapeutic biologic products.

The two new CDER offices established for review of the therapeutic biologics include the OND, Office of Drug Evaluation VI (ODE VI), and the OPS, Office of Biotechnology Products (OBP). Within ODE VI, the following divisions were established: Division of Therapeutic Biological Oncology Products, Division of Therapeutic Biological Internal Medicine Products, and Division of Review Management and Policy. Within OBP, the following divisions were established: Division of Monoclonal Antibodies and Division of Therapeutic Proteins. The delegations of authority for CBER and CDER, which give officials in the Centers the legal authority needed to take substantive actions and perform certain functions of the Commissioner of Food and Drugs, have been revised to reflect these changes.

B. Products Transferred to CDER and Products Remaining in CBER

The change in regulatory responsibility resulted in the transfer of applications to CDER for products belonging to the following product classes:

- Monoclonal antibodies for in-vivo use;
- Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except for those that are specifically assigned to CBER (e.g., vaccines and blood products). This category includes therapeutic proteins derived from plants, animals, or microorganisms, and recombinant versions of these products;
- Immunomodulators (nonvaccine and nonallergenic products intended to treat disease by inhibiting or modifying a preexisting immune response); and
- Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of hematopoietic cells in vivo.[1]

The following biological product classes remain at CBER:

- Cellular products, including products composed of human, bacterial or animal cells (such as pancreatic islet cells for transplantation), or from physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines);
- Allergenic extracts used for the diagnosis and treatment of allergic diseases and allergen patch tests;
- Antitoxins, antivenins, and venoms;
- Vaccines (products intended to induce or increase an antigen specific immune response for prophylactic or therapeutic immunization, regardless of the composition or method of manufacture);
- Blood, blood components, plasma derived products (e.g., albumin, immunoglobulins, clotting factors, fibrin sealants, proteinase inhibitors), including recombinant and transgenic versions of plasma derivatives (e.g., clotting factors), blood substitutes,

[1] Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease or otherwise alter the production of hematopoietic cells in vivo, for the purpose of being harvested for use in the production of a therapeutic cellular or blood product, may be regulated in combination with the therapeutic cellular or blood product, as appropriate. Sponsors of products that fit this description should contact the center jurisdiction officers for guidance on appropriate center assignment.