options that would minimize any significant impact of a rule on small entities. FDA estimates that the final rule will not impose any compliance costs on the animal drug industry, but rather expects it to provide a small cost savings for any company submitting an NADA for an animal drug to be used in sheep. Because this final rule makes no mandates on other government entities and will result in expenditures less than $100 million in any one year, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Discussion

The benefit of this final rule will be to lessen the preapproval study requirements of NADA's for animal drugs to be used in sheep. It is therefore expected to lower research expenses and provide an impetus for sponsors to submit NADA's for minor use species rather than rely on extra-label use of animal drugs on sheep. More specifically, it would eliminate the need for a radio-labeled total residue study that can be costly and prohibitive for sponsors of new animal drugs for small markets such as sheep. FDA believes this study is unnecessary in this instance due to the similarities in the metabolism of most drugs in cattle and sheep. A more flexible approach that allows for this interspecies data extrapolation, along with the continued residue depletion studies, would encourage NADA submissions by decreasing research costs while continuing to protect human food safety. Apart from these cost savings, FDA does not expect this final rule to impose any other compliance burdens on sponsors of new animal drugs.

FDA is amending the animal drug regulations to reclassify sheep as a minor species for all data collection purposes, thereby allowing extrapolation of data from closely related species such as cattle to sheep. Currently, FDA considers sheep as a minor species for the purpose of the data necessary to demonstrate animal safety and effectiveness only. It currently considers sheep as a major species for the purpose of human food safety requirements. Because new data have led FDA to believe there are not significant differences in the metabolism of most drugs between ruminant species, FDA is reclassifying sheep as a minor species for all data collection purposes. Thus, most data packages supporting an NADA for use in sheep will be able to rely on the required human food safety data collected for cattle.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. In the proposed rule, the agency mistakenly made this determination under 21 CFR 25.33(d)(4), which applies to action on minor species NADA's.

VI. The Paperwork Reduction Act of 1995

The NADA's regulation, § 514.1, contains collections of information requirements previously approved under OMB Control No. 0910–0032. FDA is amending the new animal drug regulation to reclassify sheep as a minor species for all data collection purposes. This reclassification does not change the reporting or recordkeeping burden, thus clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, 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 part 514 is amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Section 514.1 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 514.1 Applications.

* * * * *

(d) * * *

(1) * * *

(ii) *Minor species* means animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats.

* * * * *

Dated: July 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19627 Filed 8–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00P–1117]

Medical Devices; Anesthesiology Devices; Classification of Devices to Relieve Upper Airway Obstruction; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of June 23, 2000 (65 FR 39098). The document classified devices to relieve acute upper airway obstruction. These type devices were classified into class II. The preamble to the final rule correctly states that the devices were exempt from premarket notification, but this exemption was not reflected in the regulatory text. This document corrects that error.

DATES: This rule is effective August 3, 2000.

FOR FURTHER INFORMATION CONTACT: Carroll O'Neill, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262, ext. 170.

SUPPLEMENTARY INFORMATION: In FR Doc. 00–15864, appearing on page 39098 in the **Federal Register** of June 23, 2000, the following correction is made:

§ 868.5115 [Corrected]

On page 39099, in the third column, in § 868.5115 *Device to relieve acute upper airway obstruction*, in paragraph (b), insert at the end of the paragraph the sentence ''The device is exempt

from the premarket notification procedures in subpart E of part 807 of this chapter, subject to § 868.9.''

Dated: July 17, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–19593 Filed 8–2–00; 8:45 am]

BILLING CODE 4160–01–F

SELECTIVE SERVICE SYSTEM

32 CFR Part 1615

Change of Agency Address To Request a Verification Notice

AGENCY: Selective Service System.

ACTION: Final rule; technical amendment.

SUMMARY: This technical amendment to the rule on administration of registration changes the Selective Service System (SSS) address for registrants to contact if they do not receive a verification notice from SSS within 90 days after completing and submitting a Registration Card. The present address in the Code of Federal Regulations is outdated due to a change of location for the Agency's headquarters and its Data Management Center.

DATES: Effective September 5, 2000.

FOR FURTHER INFORMATION CONTACT: Rudy Sanchez, Office of the General Counsel, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425. (703–605–4071).

SUPPLEMENTARY INFORMATION: The SSS considers this rule (32 CFR part 1615) to be a procedural rule which is exempt from the notice-and-comment under 5 U.S.C. 533(b)(3)(A). This rule is not a significant rule for the purpose of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, SSS certifies that these regulatory amendments will not have a significant impact on small business entities.

Lists of Subjects in 32 CFR Part 1615

Selective Service System.

For the reason set forth in the preamble, amend part 1615 of title 32 of the Code of Federal Regulations as follows:

PART 1615—ADMINISTRATION OF REGISTRATION

1. The authority citation for part 1615 continues to read as follows:

Authority: Military Selective Service Act, 50 U.S.C. 451 *et seq.* and E.O. 11623.

§ 1615.1 [Amended]

2. In § 1615.1(b), revise ''600 E Street, NW., Washington, DC 20435'' to read ''P.O. Box 94638, Palatine, IL 60094–4638''.

Dated: July 28, 2000.

Gil Coronado,

Director.

[FR Doc. 00–19514 Filed 8–2–00; 8:45 am]

BILLING CODE 8015–01–U

SELECTIVE SERVICE SYSTEM

32 CFR Part 1698

Change of Agency Address To Request an Advisory Opinion

AGENCY: Selective Service System.

ACTION: Final rule; technical amendment.

SUMMARY: This technical amendment to the rule on advisory opinions changes the Selective Service System (SSS) address for persons to request an advisory opinion regarding the liability or obligation to register under the Military Selective Service Act. The present address listed in the Code of Federal Regulations to request advisory opinions is outdated due to a change of location for the Agency's headquarters and its Data Management Center.

DATES: Effective September 5, 2000.

FOR FURTHER INFORMATION CONTACT: Rudy Sanchez, Office of the General Counsel, Selective Service System, 1515 Wilson Boulevard, Arlington, VA 22209–2425. (703–605–4071).

SUPPLEMENTARY INFORMATION: The SSS considers this rule (32 CFR part 1698) to be a procedural rule which is exempt from the notice-and-comment under 5 U.S.C. 533(b)(3)(A). This rule is not a significant rule for the purpose of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, SSS certifies that these regulatory amendments will not have a significant impact on small business entities.

Lists of Subjects in 32 CFR Part 1698

Administrative practice and procedure, Selective Service System.

For the reason set forth in the preamble, amend part 1698 of title 32 of the Code of Federal Regulations as follows:

PART 1698—ADVISORY OPINIONS

1. The authority citation for part 1698 continues to read as follows:

Authority: Military Selective Service Act, 50 U.S.C. 451 *et seq.*; E.O. 11623.

§ 1698.2 [Amended]

2. In § 1698.2(b), revise ''ATTN: GCAO, Washington, DC 20435'' to read ''ATTN: SIL, P.O. Box 94638, Palatine, IL 60094–4638''.

Dated: July 28, 2000.

Gil Coronado,

Director.

[FR Doc. 00–19515 Filed 8–2–00; 8:45 am]

BILLING CODE 8015–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 413 and 419

[HCFA–1005–IFC]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services: Revisions to Criteria to Define New or Innovative Medical Devices, Drugs, and Biologicals Eligible for Pass-Through Payments and Corrections to the Criteria for the Grandfather Provision for Certain Federally Qualified Health Centers

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period changes one criterion and postpones the effective date for two other criteria that a new device, drug, or biological must meet in order for its cost to be considered ''not insignificant'' for purposes of determining its eligibility for transitional pass-through payments. It also changes the transitional pass-through payment policy to include new single use medical devices that come in contact with human tissue and that are surgically implanted or inserted in a patient whether or not the devices remain with the patient after the patient is released from the hospital outpatient department. These policies represent a departure from those presented in the April 7, 2000 **Federal Register** final rule with comment period entitled, ''Prospective Payment System for Hospital Outpatient Services''.

This interim final rule with comment period also corrects a trigger date for grandfathering of provider-based Federally Qualified Health Centers (FQHCs) to conform with the intent not to disrupt existing FQHCs with longstanding provider-based treatment that we discussed in the April 2000