

required. As a result, the airspace legal description must be amended. This rule will become effective on the date specified in the **EFFECTIVE DATE** section. Since this action eliminates the impact of controlled airspace on the users of the airspace in the vicinity of the Ocracoke Island Airport, Ocracoke, NC, notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) amends Class E5 airspace at Ocracoke, NC.

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 "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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by Reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, 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 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth

* * * * *

ASO NC E5 Ocracoke, NC [Revised]

Ocracoke Island Airport, NC
(Lat. 35°06'05"N., long. 75°57'58"W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Ocracoke Island Airport.

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Issued in College Park, Georgia, on August 8, 2001.

Wade T. Carpenter,
*Acting Manager, Air Traffic Division,
Southern Region.*

[FR Doc. 01–22246 Filed 9–4–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a

change of sponsor's name and address for Baxter Pharmaceutical Products, Inc.

DATES: This rule is effective September 5, 2001.

ADDRESSES: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Baxter Pharmaceutical Products, Inc., 110 Allen Rd., Liberty Corner, NJ 07938, has informed FDA of a change of name and address to Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the changes.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for "Baxter Pharmaceutical Products, Inc." and in the table in paragraph (c)(2) by revising the entry for "010019" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	* * * * *
Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974	010019
* * * * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
* * * * *	* * * * *
010019	Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974
* * * * *	* * * * *

Dated: August 23, 2001.
Claire M. Lathers,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
 [FR Doc. 01-22167 Filed 9-4-01; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Dow B. Hickam, Inc., to Bertek Pharmaceuticals, Inc.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

SUPPLEMENTARY INFORMATION: Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035, has informed FDA that it has transferred to Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478, ownership of, and all rights and interests in NADA 39-583. Accordingly, the agency is amending the regulations in 21 CFR 524.2620 to reflect the transfer of ownership.

In addition, Bertek Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) is being amended to add entries for the firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

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 parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Dow B. Hickam, Inc." and by alphabetically adding an entry for "Bertek Pharmaceuticals, Inc." and in the table in paragraph (c)(2) by removing the entry for "000514" and by numerically adding an entry for "062794" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	* * * * *
Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478	062794
* * * * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
* * * * *	* * * * *
062794	Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478
* * * * *	* * * * *