

FDC Date	State	City	Airport	FDC Number	SIAP
04/23/98	AR	West Memphis.	West Memphis Muni .....	FDC 8/2427	NDB RWY 17, AMDT 10
04/23/98	IN	North Vernon.	North Vernon .....	FDC 8/2421	GPS RWY 23, ORIG
04/23/98	MD	Salisbury	Ocean City Wicomico Regional .....	FDC 8/2416	ILS RWY 32, AMDT 5A
04/23/98	NC	Charlotte	Charlotte/Douglas Intl .....	FDC 8/2397	ILS RWY 36R (CAT I,II AND III), AMDT 8
04/23/98	NH	Concord	Concord Muni .....	FDC 8/2429	ILS RWY 35, AMDT 1
04/23/98	NJ	Teterboro	Teterboro .....	FDC 8/2399	ILS RWY 6, AMDT 28
04/23/98	NJ	Teterboro	Teterboro .....	FDC 8/2400	COPTER ILS RWY 6, ORIG
04/23/98	NJ	Teterboro	Teterboro .....	FDC 8/2401	NDB OR GPS RWY 6, AMDT 17A
04/23/98	NJ	Teterboro	Teterboro .....	FDC 8/2402	VOR/DME OR GPS-B, AMDT 2
04/23/98	VA	Franklin	Franklin Muni-John Beverly Rose .....	FDC 8/2442	VOR/DME OR GPS RWY 27, AMDT 9
04/23/98	WV	Charleston.	Yeager .....	FDC 8/2415	ILS RWY 5, AMDT 4
04/24/98	LA	New Orleans.	New Orleans Intl (Moisant Field) .....	FDC 8/2468	LOC RWY 19, ORIG
04/24/98	NH	Lebanon	Lebanon Muni .....	FDC 8/2463	ILS RWY 18 AMDT 4
04/27/98	NY	New York	John F. Kennedy Intl .....	FDC 8/2536	ILS RWY 31L AMDT 9A
04/28/98	FL	Jacksonville.	Jacksonville Intl .....	FDC 8/2567	ILS RWY 25 ORIG-A
04/28/98	TN	Jackson	McKellar-Sipes Regional .....	FDC 8/2568	LOC BC RWY 20 AMDT 5A
04/23/98	DH	Whitefield.	Mount Washington Regional .....	FDC 8/2430	LOC RWY 10, AMDT 4

[FR Doc. 98-12134 Filed 5-6-98; 8:45 am]  
BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 529

#### Certain Other Dosage Form New Animal Drugs; Competitive Exclusion Culture

**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 new animal drug application (NADA) filed by BioScience Division of Milk Specialties Co. The NADA provides for use of a competitive exclusion culture (lyophilized bacterial cultures) for early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization.

**EFFECTIVE DATE:** May 7, 1998.

#### FOR FURTHER INFORMATION CONTACT:

Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1659.

#### SUPPLEMENTARY INFORMATION:

BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118, is sponsor of NADA 141-101 that provides for the use of Preempt™, a competitive exclusion culture (lyophilized bacterial cultures), for the early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization. The NADA is approved as of March 13, 1998, and the regulations are amended by adding 21 CFR 529.469 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, BioScience Division of Milk Specialties Co. has not been previously listed in the animal drug regulations as sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) are amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for food-producing animals qualifies for 5 years of marketing exclusivity beginning March 13, 1998, because no active ingredient (including any salt or ester of the active ingredient) has been approved in any other application.

The agency has determined under 21 CFR 25.33(c) 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.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling,

Reporting and recordkeeping requirements.

21 CFR Part 529

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 529 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 alphabetically adding an entry for "BioScience Division of Milk Specialties Co." and in paragraph (c)(2)

by numerically adding an entry for "032761" 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
* * * * *	* * * * *
BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118	032761
* * * * *	* * * * *

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	* * * * *
032761	BioScience Division of Milk Specialties Co., Illinois and Water Sts., P.O. Box 278, Dundee, IL 60118.
* * * * *	* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 529.469 is added to read as follows:

§ 529.469 Competitive exclusion culture.

(a) Specifications. Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.

(1) For 2,000-dose packet, add contents of one 2,000-dose packet of reconstitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.

(2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.

(b) Sponsor. See No. 032761 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) Conditions of use. Chickens—(1) Amount. Apply 25 milliliters of reconstituted culture as a topical spray on each tray of 100 chicks (0.25 milliliter per chick).

(2) Indications for use. For early establishment of intestinal microflora in chickens to reduce Salmonella colonization.

(3) Limitations. Administer as soon as possible after hatch, preferably at less than 1 day of age. Expose chicks to light for at least 5 minutes after spray treatment to encourage preening for oral uptake of the organisms. Provide access to feed and water as soon as possible after treatment. Do not administer antibiotics to treated chickens.

Dated: April 22, 1998.

Stephen F. Sundlof,  
Director, Center for Veterinary Medicine.  
[FR Doc. 98-12056 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-08-015]

RIN 2115-AA97

Safety Zone; Greenwood Lake Powerboat Classic, Greenwood Lake, New Jersey

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a powerboat race located on Greenwood Lake, New Jersey. This safety zone is in effect from 10 a.m. until 7 p.m. on Saturday, May 16, and Sunday, May 17, 1998. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in the southern end of Greenwood Lake, New Jersey.

DATES: This temporary final rule is effective from 10 a.m. until 7 p.m. on Saturday, May 16, and Sunday, May 17, 1998.