(e) *Restrictions.* (1) Except for the transit provisions provided for in paragraph (f) of this section, a vessel issued a valid Category F permit may only fish for, possess, and land monkfish in or from the Offshore Fishery Program Area while on a monkfish DAS.

(2) A vessel enrolled in the Offshore Fishery Program is restricted to fishing under its monkfish DAS during the season in paragraph (d) of this section.

(3) A vessel issued a Category F permit that is fishing on a monkfish DAS is subject to the minimum mesh size requirements applicable to limited access monkfish Category A and B vessels, as specified under § 648.91(c)(1)(i) and (c)(1)(iii), as well as the other gear requirements specified in paragraphs (c)(2) and (c)(3).

(4) A vessel issued a Category F permit must have installed on board an operational VMS unit that meets the minimum performance criteria specified in §§ 648.9 and 648.10 during the entire season established under paragraph (d) of this section. Unless otherwise required to maintain an operational VMS unit under the VMS notification requirements specified at § 648.10(b)(1), a vessel issued a Category F permit may turn off its VMS unit outside of this season.

(f) *Transiting.* A vessel issued a Category F permit and fishing under a monkfish DAS that is transiting to or from the Offshore Fishery Program Area, described in paragraph (c)(1) of this section, shall have all gear stowed and not available for immediate use in accordance with the gear stowage provisions specified under § 648.23(b).

(g) *Monkfish possession limits and DAS allocations.* (1) A vessel issued a Category F permit may land up to 1,600 lb (726 kg) tail weight or 5,312 lb (2,409 kg) whole weight of monkfish per monkfish DAS (or any prorated combination of tail weight and whole weight based on the conversion factor of 3.32).

(2) The monkfish DAS allocation for vessels issued a Category F permit shall be equal to the trip limit applicable to the vessel's monkfish limited access permit category divided by the fixed daily possession limit specified in paragraph (g)(1) of this section, and then multiplied by the DAS allocation for limited access monkfish vessels not issued Category F permits, specified under § 648.92(b)(1). For example, if a vessel has a limited access monkfish Category C permit, and the applicable trip limit is 800 lb (363 kg) for this category, and the vessel has an annual allocation of 40 monkfish DAS, then the monkfish DAS allocated to that vessel when issued a Category F permit would be 20 monkfish DAS (800 lb divided by 1,600 lb, multiplied by 40 monkfish DAS equals 20 DAS). Any carryover monkfish DAS will be included in the calculation of monkfish DAS for Category F vessels.

(3) Vessels issued a Category F permit that are fishing under a NE multispecies DAS in the NFMA are subject to the incidental catch limit specified in paragraph (c)(1)(i) of this section.

(h) *DAS usage by NE multispecies or sea scallop limited access permit holders.* A vessel issued a Category F permit that also has been issued either a NE multispecies or sea scallop limited access permit, and is fishing on a monkfish DAS, is subject to the DAS usage requirements specified in § 648.92(b)(2).

■ 17. In § 648.96, paragraph (c)(1)(i) is revised to read as follows:

§ 648.96 Monkfish annual adjustment process and framework specifications.

* * * * *

(c) * * *

(1) * * *

(i) Based on their annual review, the MFMC may develop and recommend, in addition to the target TACs and management measures established under paragraph (b) of this section, other options necessary to achieve the Monkfish FMP's goals and objectives, which may include a preferred option. The MFMC must demonstrate through analysis and documentation that the options it develops are expected to meet the Monkfish FMP goals and objectives. The MFMC may review the performance of different user groups or fleet sectors in developing options. The range of options developed by the MFMC may include any of the management measures in the Monkfish FMP, including, but not limited to: Closed seasons or closed areas; minimum size limits; mesh size limits; net limits; liver-to-monkfish landings ratios; annual monkfish DAS allocations and monitoring; trip or possession limits; blocks of time out of the fishery; gear restrictions; transferability of permits and permit rights or administration of vessel upgrades, vessel replacement, or permit assignment; measures to minimize the impact of the monkfish fishery on protected species; gear requirements or restrictions that minimize bycatch or bycatch mortality; transferable DAS programs; and other frameworkable measures included in §§ 648.55 and 648.90.

* * * * *

■ 18. Section 648.97 is added to subpart F to read as follows:

§ 648.97 Closed areas.

(a) *Oceanographer Canyon Closed Area.* No fishing vessel or person on a fishing vessel may enter, fish, or be in the area known as Oceanographer Canyon Closed Area (copies of a chart depicting this area are available from the Regional Administrator upon request), as defined by straight lines connecting the following points in the order stated, while on a monkfish DAS:

OCEANOGRAPHER CANYON CLOSED AREA

Point	N. Lat.	W. Long.
(1) OC1	40°10′	68°12′
(2) OC2	40°24′	68°09′
(3) OC3	40°24′	68°08′
(4) OC4	40°10′	67°59′
(5) OC1	40°10′	68°12′

(b) *Lydonia Canyon Closed Area.* No fishing vessel or person on a fishing vessel may enter, fish, or be in the area known as Lydonia Canyon Closed Area (copies of a chart depicting this area are available from the Regional Administrator upon request), as defined by straight lines connecting the following points in the order stated, while on a monkfish DAS:

LYNDONIA CANYON CLOSED AREA

Point	N. Lat.	W. Long.
(1) LC1	40°16′	67°34′
(2) LC2	40°16′	67°42′
(3) LC3	40°20′	67°43′
(4) LC4	40°27′	67°40′
(5) LC5	40° 27′	67°38′
(6) LC1	40°16′	67°34′

[FR Doc. 05–8450 Filed 4–26–05; 2:21 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Penicillin G Benzathine and Penicillin G Procaine Sterile Suspension

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 Cross Vetpharm Group Ltd. The supplemental NADA provides for the addition of

statements to labeling of an injectable penicillin suspension warning against the use of this product in calves to be processed for veal. FDA is also amending the regulations to correctly identify approved indications for use for several penicillin products. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective April 28, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to NADA 65–506 that provides for the addition of statements to labeling of COMBI–PEN–48 (penicillin G benzathine and penicillin G procaine) injectable suspension warning against the use of this product in calves to be processed for veal. The supplemental NADA is approved as of March 23, 2005, and the regulations are amended in § 522.1696a (21 CFR 522.1696a) to reflect the approval. FDA is also amending § 522.1696a to correct an error in the indications for use for several penicillin products which was introduced during reformatting of this section in 2001 (66 FR 711, January 4, 2001). This is being done to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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 522

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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.1696a is amended by revising the section heading and paragraphs (b)(2), (b)(3), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(2) Nos. 010515, 059130, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Limit treatment to two doses. Not for use within 30 days of slaughter. For Nos. 010515, 049185, 059130, and 061623: A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: April 8, 2005.

Stephen D. Vaughn,

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

[FR Doc. 05–8510 Filed 4–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2002P–0520] (formerly Docket No. 02P–0520)

Dental Devices; Reclassification of Tricalcium Phosphate Granules and Classification of Other Bone Grafting Material for Dental Bone Repair

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying tricalcium phosphate (TCP) granules for dental bone repair from class III to class II (special controls), classifying into class II (special controls) other bone grafting material for dental indications, and revising the classification name and identification of the device type. Bone grafting materials that contain a drug that is a therapeutic biologic will remain in class III and continue to require a premarket approval application. The classification identification includes materials such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for the class II devices.

EFFECTIVE DATE: May 31, 2005.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, e-mail: *michael.adjodha@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after the following requirements are met: (1) FDA has received a recommendation from a device classification panel (an FDA advisory committee); (2) FDA has published the panel's recommendation