22 SIAP and RNAV (GPS) 26 SIAP to Barstow-Daggett Airport, Daggett, CA.

Interested parties were invited to participate in this rulemaking, proceeding by submitting written comments on the proposed to the FAA. No comments to the proposal were received. Class E airspace designations for airspace extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, 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 14 CFR part 71 modifies the Class E airspace area at Daggett, CA. The establishment of a RNAV (GPS) RWY 22 SIAP and RNAV RWY 26 SIAP to Barstow-Daggett Airport has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the RNAV (GPS) RWY 22 SIAP and RNAV (GPS) RWY 26 SIAP to Barstow-Daggett Airport, Daggett, CA.

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 12766; (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; E.O. 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 the Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

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

* * * * *

AWP CA E5 Daggett, CA [Revised]

Barstow-Daggett Airport, CA
(Lat. 34°51′13″ N, long. 116°47′12″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Barstow-Daggett Airport and within 2.2 miles each side of the 057° bearing from the Barstow-Daggett Airport extending from the 6.5-mile radius to 11.8 miles northeast of the airport.

Issued in Los Angeles, California, on April 8, 2002.

John Clancy,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 02–10499 Filed 4–29–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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 Boehringer Ingelheim Vetmedica, Inc., to Alpharma, Inc.

DATES: This rule is effective April 30, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 39–077 for CSP (chlortetracycline, sulfathiazole, penicillin) 250 and CSP 500 Type A medicated articles to Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024. Accordingly, the agency is amending the regulations in 21 CFR 558.155 to reflect the change of sponsor.

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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.155 [Amended]

1. Section 558.155 *Chlortetracycline, sulfathiazole, penicillin* is amended in paragraphs (a)(1) and (a)(2) by removing ''Nos. 000010 and 046573'' and by adding in its place ''No. 046573''.

Dated: February 22, 2002.

Claire M. Lathers,

Director, Office of New Animal Drugs, Center for Veterinary Medicine.

[FR Doc. 02–10511 Filed 4–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 99P–1864]

Orthopedic Devices: Reclassification of the Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the hip joint metal/polymer constrained cemented or uncemented prosthesis intended to replace a hip joint from class III (premarket approval) to class II (special controls). FDA is also

identifying the guidance document entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/ Polymer Constrained Cemented or Uncemented Prosthesis'' as the special control that the agency believes will reasonably ensure the safety and effectiveness of the device. This reclassification is being undertaken based on new information regarding the device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA), under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 Amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Moderization Act of 1997 (FDAMA). FDA is also revising the device identification to accurately describe the device.

DATES: This regulation is effective May 30, 2002.

FOR FURTHER INFORMATION CONTACT: John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 6, 2001 (66 FR 46563), FDA published a proposed rule to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis from class III to class II based on new information respecting the device. FDA identified the guidance document entitled ''Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' as the special control capable of providing reasonable assurance of safety and effectiveness for the device.

Interested persons were given until December 5, 2001, to comment on the proposed rule. FDA received three comments. Two comments commended FDA's proposal to reclassify these devices and agreed that the guidance proposed as the special control was adequate to provide reasonable assurance of the safety and effectiveness of the device.

One comment stated that FDA's proposed special control was inadequate to protect against certain types of device failure, specifically shell-bone interface failure that may occur after implantation of this highly constrained device. The comment stated that this risk to health could only be addressed through a clinical testing requirement in a premarket approval application. The comment stated that the proposed rule was legally and procedurally flawed because FDA failed to address this specific risk to health in the proposed rule.

FDA disagrees with the comment. FDA agrees that shell-bone interface failure may occur after implantation of the device. FDA notes that the Orthopedic and Rehabilitation Devices Panel (the Panel) discussed this specific risk to health at the Panel meeting held on November 4, 1999, that was cited in the September 6, 2001, proposed rule to reclassify the device. Their recommendation to reclassify the device from class III into class II was made in full awareness of this risk to health because the Panel believed that this risk to health could be controlled through implementation of special controls. Although clinical trials were discussed at the meeting, the Panel did not recommend that clinical trials be a special control to reasonably assure the safety and effectiveness of this device. The agency concurred with the Panel's recommendation. The ''Risks to Health'' section of the proposed rule included a discussion of possible revision and of pain and/or loss of function due to a variety of causes, including device failure. The agency believes that discussion of device failure, as well as discussion of device failure in the draft guidance, logically included device failures that were the result of problems with the shell-bone interface. Although FDA did not specifically state that the first bulleted precaution statement in the draft guidance document was intended to address the risk of this specific device failure, the agency believes that the scope of the precaution statement in the draft guidance document did cover this risk. In order to provide additional clarity, FDA has revised this precaution statement in the final guidance document. Because the agency believes its proposed rule and draft guidance raised the concerns associated with this risk and because the final guidance includes further clarification, FDA does not agree that the proposed rule was legally or procedurally flawed.

II. FDA's Conclusion

Based on a review of the available information referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that the special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. The agency is also revising the device identification to accurately describe the currently marketed device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Moreover, compliance with special controls for these devices will not impose significant new costs on affected manufacturers because most of these devices already comply with the special controls. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of

$100 million or more on either the private sector or State, local, or tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. 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 Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3310 is revised to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.''

Dated: April 15, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–10509 Filed 4–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–225–FOR]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Kentucky regulatory program (the ''Kentucky program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky is proposing revisions to the Kentucky Revised Statute (KRS) 350.085(6) to reaffirm, with some modifications, the circumstances under which the regulatory authority may not issue a permit, based upon ownership and control of an operation with an unabated violation. This rule addresses the permit block provisions. The remaining provision will be addressed in a future rulemaking (KY–234–FOR).

EFFECTIVE DATE: April 30, 2002.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Field Office Director; Telephone: (859) 260–8400; E-mail: *bkovacic@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program
II. Submission of the Proposed Amendment
III. OSM's Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Kentucky Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act ***; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. You can find background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and conditions of approval in the May 18, 1982 **Federal Register** (47 FR 21404). You can also find later actions concerning Kentucky's program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16, and 917.17.

II. Submission of the Proposed Amendment

By letter dated May 9, 2000 (administrative record no. KY–1473), Kentucky sent us an amendment to its approved SMCRA regulatory program. The amendment, which includes only changes that the Commonwealth is making on its own initiative, concerns permit blocking, easements of necessity, and revisions to KRS 350.445(3) to address roads above highwalls.

In this rulemaking, we are addressing only the permit block provisions. We announced our decision on the easement of necessity provision in a rule published on June 20, 2001 (66 FR 33020). The provision concerning roads above highwalls will be addressed in a future rulemaking.

We announced receipt of the proposed amendment in the May 31, 2000, **Federal Register** (65 FR 34625). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on June 30, 2000. We received several comments from industry groups addressing various parts of the amendment, but only one commenter representing an environmental council addressed the ownership and control provisions.