

(c) *Certificate of Service.* The appellant must attach to the appeal petition a signed certificate of service meeting the requirements of § 134.204(d).

§ 134.506 What are the service and filing requirements?

The provisions of § 134.204 apply to the service and filing of all pleadings and other submissions permitted under this subpart unless otherwise indicated in this subpart.

§ 134.507 When does the AA/GC transmit the protest file and to whom?

Upon receipt of an appeal petition, the AA/GC will send to OHA a copy of the protest file relating to that determination. The AA/GC will certify and authenticate that the protest file, to the best of his or her knowledge, is a true and correct copy of the protest file.

§ 134.508 What is the standard of review?

The standard of review for an appeal of a SDVO SBC protest determination is whether the AA/GC's determination was based on clear error of fact or law. With respect to status determinations on whether the owner is a veteran, service-disabled veteran, or veteran with a permanent and severe disability, the Judge will not review the determinations made by the U.S. Department of Veteran's Affairs, U.S. Department of Defense, or such determinations identified by documents provided by the U.S. National Archives and Records Administration.

§ 134.509 When will a Judge dismiss an appeal?

(a) The Judge selected to preside over a protest appeal shall dismiss the appeal, if:

(1) The appeal does not, on its face, allege facts that if proven to be true, warrant reversal or modification of the determination;

(2) The appeal petition does not contain all of the information required in § 134.505;

(3) The appeal is untimely filed pursuant to § 134.503 or is not otherwise filed in accordance with the requirements of this subpart or the requirements in Subparts A and B of this part; or

(4) The matter has been decided or is the subject of an adjudication before a court of competent jurisdiction over such matters.

(b) Once Appellant files an appeal, subsequent initiation of litigation of the matter in a court of competent jurisdiction will not preclude the Judge from rendering a final decision on the matter.

§ 134.510 Who can file a response to an appeal petition and when must such a response be filed?

Although not required, any person served with an appeal petition may file and serve a response supporting or opposing the appeal if he or she wishes to do so. If a person decides to file a response, the response must be filed within 7 business days after service of the appeal petition. The response should present argument.

§ 134.511 Will the Judge permit discovery and oral hearings?

Discovery will not be permitted and oral hearings will not be held.

§ 134.512 What are the limitations on new evidence?

The Judge may not admit evidence beyond the written protest file nor permit any form of discovery. All appeals under this subpart will be decided solely on a review of the evidence in the written protest file, arguments made in the appeal petition and response(s) filed thereto.

§ 134.513 When is the record closed?

The record will close when the time to file a response to an appeal petition expires pursuant to 13 CFR 134.510.

§ 134.514 When must the Judge issue his or her decision?

The Judge shall issue a decision, insofar as practicable, within 15 business days after close of the record. If OHA does not issue its determination within the 15-day period, the contracting officer may award the contract, unless the contracting officer has agreed to wait for a final determination from the Judge.

§ 134.515 What are the effects of the Judge's decision?

(a) A decision of the Judge under this subpart is the final agency decision and is binding on the parties. For the effects of the decision on the contract or procurement at issue, please see 13 CFR 125.28.

(b) The Judge may reconsider an appeal decision within 20 calendar days after service of the written decision. Any party who has appeared in the proceeding, or SBA, may request reconsideration by filing with the Judge and serving a petition for reconsideration on all the parties to the appeal within 20 calendar days after service of the written decision. The request for reconsideration must clearly show an error of fact or law material to the decision. The Judge may also reconsider a decision on his or her own initiative.

(c) The Judge may remand a proceeding to the AA/GC for a new SDVO SBC determination if the latter fails to address issues of decisional significance sufficiently, does not address all the relevant evidence, or does not identify specifically the evidence upon which it relied. Once remanded, OHA no longer has jurisdiction over the matter, unless a new appeal is filed as a result of the new SDVO SBC determination.

Dated: December 1, 2004.

Hector V. Barreto,
Administrator.

[FR Doc. 05-3445 Filed 2-23-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Euthanasia Solution

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 an original abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of an injectable solution of pentobarbital sodium and phenytoin sodium for humane, painless, and rapid euthanasia of dogs.

DATES: This rule is effective February 24, 2005.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed ANADA 200-280 that provides for use of EUTHANASIA III (pentobarbital sodium and phenytoin sodium) Solution for humane, painless, and rapid euthanasia of dogs. Med-Pharmex, Inc.'s EUTHANASIA-III Solution is approved as a generic copy of Schering-Plough Animal Health Corp.'s BEUTHANASIA-D Special, approved under NADA 119-807. The ANADA is approved as of February 3, 2005, and the regulations are amended in 21 CFR 522.900 to reflect the approval. The

basis of approval is discussed in the freedom of information summary.

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 522.900 is amended by revising paragraph (b)(1) to read as follows:

§ 522.900 Euthanasia solution.

* * * * *

(b) * * *

(1) Nos. 000061, 051259, and 051311 for use of product described in paragraph (a)(1) of this section.

* * * * *

Dated: February 15, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05-3595 Filed 2-23-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 19 and 20

RIN 2900-AL96

Board of Veterans' Appeals: Appeals Regulations, Rules of Practice; Delegations of Authority

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA), Board of Veterans' Appeals (Board) Appeals Regulations and Rules of Practice. The amendments update regulations governing certain delegations of authority exercised by the Chairman of the Board. The amendments reflect statutory changes and changes to other regulations made because of the statutory changes.

DATES: *Effective Date:* February 24, 2005.

FOR FURTHER INFORMATION CONTACT:

Steven L. Keller, Senior Deputy Vice Chairman, Board of Veterans' Appeals, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, telephone 202-565-5978.

SUPPLEMENTARY INFORMATION: The Board of Veterans' Appeals (Board) is the component of the Department of Veterans Affairs, in Washington, DC, that decides appeals from denials of claims for veterans' benefits. The Board is under the administrative control and supervision of a Chairman directly responsible to the Secretary of Veterans Affairs. 38 U.S.C. 7101. This document amends the Board's Appeals Regulations and Rules of Practice concerning delegations of authority exercised by the Chairman.

Under 38 CFR 19.14 and 20.102, certain authorities exercised by the Chairman of the Board are delegated to certain other employees of the Board. The sources of these authorities are 38 U.S.C. 7101(a), 7102, 7103, and 7104.

In 1994, 38 U.S.C. 7102 was amended to authorize the deciding of appeals by individual Board members, as well as by panels of at least three Board members. The amendment also prohibited a proceeding before the Board from being assigned to the Chairman as an individual member. Board of Veterans' Appeals Administrative Procedures Improvement Act of 1994, Public Law 103-271, § 6(a), 108 Stat. 740, 741. In May 1996, the Secretary amended the Board's Appeals Regulations and Rules of Practice to incorporate these statutory changes. See 61 FR 20447, May 7, 1996. However, certain provisions governing

the Chairman's delegation of authority in the appeals regulations and rules of practice were not amended to reflect the statutory and regulatory changes. Therefore, we are now amending 38 CFR 19.14 and 20.102 to reflect those prior statutory and regulatory changes.

The 1996 rulemaking included amendments to 38 CFR 19.3, 19.11, 20.606, 20.608, and 20.900. The amendments reflected, in addition to the statutory amendments, administrative changes in the Board's organization from sections to teams. The versions of 38 CFR 19.14 and 20.102 in effect until February 24, 2005, refer to paragraphs in the previously amended regulations that were removed, redesignated, or revised by the 1996 rulemaking.

We are removing references to § 19.3(c) and (d) from 38 CFR 19.14 because the 1996 amendments revised § 19.3 so that it has no paragraph (c) or (d).

We are also removing paragraph (a) of 38 CFR 20.102 and redesignating paragraphs (b) and (c) of § 20.102 as paragraphs (a) and (b), respectively. The provisions of paragraph (a) of 38 CFR 20.102 in effect until February 24, 2005 permitted the Vice Chairman of the Board to exercise the same authority the Chairman may exercise under 38 CFR 20.900(c). However, § 20.900(c), itself authorizes the Vice Chairman to exercise that authority as well as to delegate such authority to a Deputy Vice Chairman. Therefore, paragraph (a) of § 20.102 is not necessary.

In addition, we are removing the references to Rule 608(b) and § 20.608(b) from § 20.102(b). The provisions of paragraph (b) of § 20.102 in effect until February 24, 2005, permitted the Vice Chairman of the Board and the Deputy Vice Chairmen to exercise the same authority the Chairman may exercise under 38 CFR 20.608(b). However, the 1996 amendments removed that authority from § 20.608(b) to conform with the statutory amendments. Therefore, the references in § 20.102(b) to Rule 608(b) and § 20.608(b) are inappropriate.

Finally, in 38 CFR 20.102(c), we are replacing the references to Rule 606(e) and § 20.606(e) with references to Rule 606(d) and § 20.606(d). The provisions of paragraph (c) of § 20.102 in effect until February 24, 2005 permitted the Vice Chairman of the Board, the Deputy Vice Chairmen, or members of the Board to exercise the same authority the Chairman may exercise under 38 CFR 20.606(e). However, that authority is now in § 20.606(d). Thus, a reference to paragraph (d) instead of paragraph (e) is the appropriate reference.