to part 760 of the EAR, the related person may file an appeal with the administrative law judge. The related person may appeal the initial decision and order of the administrative law judge to the Under Secretary in accordance with the procedures set forth in § 766.21.

(ii) If the order made applicable to the related person is issued pursuant to § 766.24 of this part to prevent an imminent violation, the recommended decision and order of the administrative law judge shall be reviewed by the Under Secretary in accordance with the procedures set forth in § 766.24(e) of this part.

(iii) If the order made applicable to the related person is for a violation of the EAR not related to part 760 of the EAR and not issued pursuant to § 766.24 of this part, the recommended decision and order of the administrative law judge shall be reviewed by the Under Secretary in accordance with the procedures set forth in § 766.22 of this part.

■ 5. In § 766.24 paragraph (d)(3)(ii) is revised to read as follows:

§ 766.24 Temporary denials.

* * * * *

(d) * * *

(3) * * *

(ii) Any person designated as a related person may not oppose the issuance or renewal of the temporary denial order, but may file an appeal in accordance with § 766.23(c) of this part.

* * * * *

Dated: May 2, 2006.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 06–4420 Filed 5–11–06; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol and Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol and tylosin to make two-way combination Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective May 12, 2006.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz @fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–427 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make two-way combination Type C medicated feeds for heifers fed in confinement for slaughter. Ivy Laboratories' ANADA 200–427 is approved as a generic copy of Pharmacia and Upjohn Co.'s new animal drug application (NADA) 139–192 for combination use of MGA 500 (melengestrol acetate) Liquid Premix and TYLAN in cattle feed. The application is approved as of April 19, 2006, and the regulations are amended in 21 CFR 558.342 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that the April 1, 2005, edition of title 21, parts 500 to 599 of the Code of Federal Regulations (CFR) does not accurately reflect the approved conditions of use for melengestrol and tylosin. This error was inadvertently included in the 2002 codification of a supplement for the pioneer application (67 FR 47687, July 22, 2002). At this time, § 558.342 is being amended to correct this error. This action is being taken 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)(2) 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 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.

§ 558.342 [Amended]

■ 2. In § 558.342, amend the table in paragraphs (e)(1)(vii) and (e)(1)(ix) in the ''Limitations'' column in entry ''3.'' by removing ''(from a dry Type A article)'', and in the table in paragraph (e)(1)(ix) in the ''Sponsor'' column by numerically adding ''021641''.

Dated: May 4, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 06–4426 Filed 5–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. 2006N–0051]

Health Resources and Services Administration

42 CFR Part 121

Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation

AGENCIES: Food and Drug Administration, Health Resources and Services Administration, (HHS).

ACTION: Direct final rule.

SUMMARY: The Health Resources and Services Administration (HRSA) and the Food and Drug Administration (FDA) are amending their regulations to consider as part of an organ those blood

vessels recovered with the organ that are intended for use in organ transplantation (HRSA regulation); and to exclude such blood vessels from the definition of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (FDA regulation). We (HRSA and FDA) are taking this action to provide that blood vessels recovered with organs and intended for use in organ transplantation are governed by the regulations pertaining to organs. The regulation of other recovered blood vessels remains unchanged. We believe that this change will eliminate the unnecessary burden resulting from an organ procurement organization's efforts to comply with both FDA and HRSA rules with respect to blood vessels (FDA jurisdiction) and organs (HRSA jurisdiction). We are issuing these amendments directly as a final rule because they are noncontroversial, and there is little likelihood that we will receive any significant adverse comments. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under our usual procedures for notice and comment in the event that we receive any significant adverse comments on the direct final rule. If we receive any significant adverse comments that warrant terminating the direct final rule, we will consider such comments on the proposed rule in developing the final rule.

DATES: This rule is effective September 25, 2006. Submit written or electronic comments on the direct final rule by July 26, 2006. If we receive no comments during the specified comment period, we intend to publish a confirmation document on or before the effective date of this direct final rule confirming that the direct final rule will go into effect on September 25, 2006. If we receive any significant adverse comments during the comment period, we intend to withdraw this direct final rule before its effective date by publication of a document in the **Federal Register**.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0051, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph. FDA will share all comments received with HRSA.

Instructions: All submissions received must include the agency name (FDA) and Docket No. 2006N–0051 for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments see the ''Comments'' heading in section X of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA's rule: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

For information regarding HRSA's rule: Jim Burdick, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, rm. 12C–06, Rockville, MD 20857, 301–443–7577.

SUPPLEMENTARY INFORMATION:

I. Introduction

We are amending certain regulations to:

- Revise the definition of organ to include blood vessels (usually segments of iliac arteries and veins) recovered from an organ donor during the same recovery procedure of such organ(s) and intended for use in organ transplantation (hereinafter referred to as ''blood vessels intended for use in organ transplantation''); and
- Exclude blood vessels intended for use in organ transplantation from the definition of human cells, tissues, and cellular and tissue-based products (HCT/Ps).

By taking this action, blood vessels labeled and intended solely for use in organ transplantation will be subject to HRSA requirements in 42 CFR part 121 and any enforceable organ procurement and transplantation network (OPTN) policies established under 42 CFR part 121. This action will keep blood vessels intended for use in organ transplantation and organs under the same regulatory scheme, making blood vessels intended for use in organ transplantation readily available to meet organ transplant needs.

II. Background

HRSA oversees transplantation of organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs. An ''organ'' is ordinarily defined as a bodily part that performs a function or cooperates in an activity. Vascularized human organs for transplantation are under the purview of HRSA and are excluded from FDA's tissue regulations in §§ 1270.3(j)(4) and 1271.3(d)(1) (21 CFR 1270.3(j)(4) and 1271.3(d)(1)). Blood vessels are currently regulated by FDA. Blood vessels are included in the definition of ''human tissue'' under FDA regulations in § 1270.3(j) (applicable to tissue recovered before May 25, 2005), and in the definition of ''human cells, tissues, or cellular or tissue-based products (HCT/P's)'' in § 1271.3(d) (applicable to tissue recovered on or after May 25, 2005).

There is a routine practice of recovering blood vessels intended for use in organ transplantation during organ procurement and using such blood vessels to connect donor organ and recipient vessels. HRSA will regulate such blood vessels intended for use in organ transplantation as part of the organ under 42 CFR part 121. Therefore, the applicable provisions of 42 CFR part 121 apply. Such blood vessels do not need to be attached to the organ(s), nor transplanted simultaneously with such organs to the same recipient, nor transplanted together with the organ(s) from the same donor. Occasionally, blood vessels not used immediately for the transplantation of a donated organ are stored for a number of days and subsequently used to modify the organ

transplant in the same recipient or to accomplish transplantation in the recipient of an organ from a different donor.

Currently, FDA's jurisdiction over blood vessels intended for use in organ transplantation overlaps with HRSA's oversight of the OPTN. OPTN's membership compliance review activities are required under 42 CFR 121.10(b)(1)(iii). In addition, under 42 CFR 121.10(c), the Secretary of Health and Human Services (the Secretary) may take actions against OPTN members (including, but not limited to termination of a transplant hospital's participation in or reimbursement under Medicare and Medicaid and removal of a transplant program's designation under 42 CFR 121.9) for noncompliance with 42 CFR part 121 or enforceable OPTN policies (those approved by the Secretary) and for actions that indicate a risk to the health of patients or to the public safety. Because blood vessels intended for use in organ transplantation are recovered by Organ Procurement Organizations (OPOs) and stored temporarily at transplant centers, having two Federal inspectional programs for such facilities without a medical or public health need for such dual oversight would be inefficient and burdensome.

FDA requirements and recommendations for determining HCT/P donor eligibility are different than HRSA provisions for screening and testing organ donors. This is because of a different risk/benefit assessment for most HCT/P recipients than for vascularized human organ transplant recipients. HCT/Ps from a single donor can affect up to 100 recipients, they are often life extending, and alternative materials usually exist; whereas organs from a single donor go to fewer recipients, are almost always life saving, and are in short supply.

Therefore, in order to avoid duplication of efforts and reduce the burden on affected facilities, we are transferring jurisdiction over blood vessels intended for use in organ transplantation from FDA to HRSA. The direct final rule does not affect regulation of blood vessels intended for transplantation but not involving organ transplantation. Jurisdiction over such blood vessels remains with FDA. Ordinarily, non-organ transplant uses have a different risk/benefit assessment and the current FDA requirements are appropriate for these blood vessels.

III. Legal Authority

We are issuing these regulations under the authority of the National Organ Transplant Act as amended (NOTA) and section 361 of the Public Health Service Act (the PHS Act). NOTA authorizes HRSA, by delegation from the Secretary, to issue regulations governing the operation of the OPTN. NOTA, as amended, also authorizes the Secretary to define human organs to be covered by the OPTN. Section 374 of the PHS Act specifically states, ''[t]he term 'organ' means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation'' (42 U.S.C. 274b(d)(2)) (emphasis supplied). Accordingly, HRSA is issuing this regulation to modify the definition of ''organ,'' and to make blood vessels labeled and intended for use in the transplantation of organs subject to regulations governing the operation of the OPTN. Extending the definition of organs governed by HRSA in 42 CFR 121.2 to add blood vessels recovered with organs that are intended for use in organ transplantation, and labeled as such, furthers the Secretary's charge under NOTA.

Under the authority of section 361 of the PHS Act delegated to the Commissioner of FDA, the Department of Health and Human Services may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. This modification of FDA's existing regulation reflects FDA's re-evaluation of the level of regulation that is necessary to prevent disease transmission involving blood vessels intended for use in organ transplantation.

IV. Description of the Direct Final Rule

To transfer from FDA to HRSA jurisdiction over blood vessels intended for use in organ transplantation, we are amending 21 CFR 1271.3(d), 42 CFR 121.2, and 42 CFR 121.7 as follows.

A. 21 CFR 1271.3(d)

21 CFR 1271.3(d) defines HCT/Ps as ''articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.'' In the definition, we also identify articles not considered HCT/Ps. This direct final rule adds § 1271.3(d)(8), excluding blood vessels intended for use in organ transplantation from the definition of HCT/Ps. The rule excludes such blood vessels intended for use in organ transplantation only when they are labeled as ''For use in organ transplantation only'' to distinguish such vessels from blood vessels not intended for use in organ transplantation. By labeling such blood vessels ''For use in organ transplantation only'' we expect that they would not be used for other purposes. Under the direct final rule, blood vessels intended for other uses remain subject to 21 CFR part 1271 (or 21 CFR part 1270, for tissue recovered prior to May 25, 2005).

B. 42 CFR 121.2

Under 42 CFR 121.2, ''Organ'' means a human kidney, liver, heart, lung, or pancreas. This direct final rule adds to that definition ''Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled ''For use in organ transplantation only.'' Blood vessels intended for use in organ transplantation are required to be in compliance with HRSA provisions for donor screening and testing. The labeling provision is a distinct requirement in order for such blood vessels to fall under the regulation governing the operation of the OPTN. Any OPTN labeling policies, whether voluntary or enforceable, supplement this requirement.

C. 42 CFR 121.7

In 42 CFR 121.7, we are redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e). Under 42 CFR 121.7(e), a blood vessel intended for use in organ transplantation is subject to the allocation requirements under 42 CFR part 121 and enforceable OPTN policies pertaining to the organ with which the blood vessel is procured. These provisions apply until the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ. This allocation priority will assure that vessels that may be necessary for the immediate transplantation of the organs with which they are recovered are made available for that use prior to being diverted to other organ transplant uses.

V. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how the agency will employ direct final rulemaking. We have determined that this rule is appropriate for direct final rulemaking because we believe that it includes only noncontroversial amendments and we anticipate no significant adverse comments.

Consistent with FDA's procedures on direct final rulemaking, FDA and HRSA are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend FDA's and HRSA's regulations to include as organs those blood vessels recovered with organs that are intended for use in organ transplantation; and to exclude such blood vessels from the definition of HCT/Ps. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comments. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

We are providing a comment period of 75 days after date of publication in the **Federal Register**. If we receive any significant adverse comments, we intend to withdraw this direct final rule action before its effective date by publication of a notice in the **Federal Register**. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subjects of a significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of this direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures.

If FDA and HRSA receive no significant adverse comments during the specified comment period, FDA and HRSA intend to publish a confirmation document, before the effective date of the direct final rule, confirming the effective date.

VI. Analysis of Impacts

FDA and HRSA have examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), 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). FDA and HRSA believe that this direct final rule is not a significant regulatory action as defined by the Executive order.

Under the Regulatory Flexibility Act, agencies analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agencies do not expect that the transfer of jurisdiction over the blood vessels described in this rule from FDA to HRSA will result in substantial changes in the way transplant hospitals and OPOs preserve, store, and transplant such blood vessels, FDA and HRSA certify that the direct final rule will not have a significant economic impact on a substantial number of small entities.

Under section 202(a) of the Unfunded Mandates Reform Act of 1995, agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA and HRSA do not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Paperwork Reduction Act of 1995

This direct final rule contains no collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VIII. Environmental Impact

FDA and HRSA have determined under 21 CFR 25.30(j) 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.

IX. Federalism

FDA and HRSA have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA and HRSA have 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, FDA and HRSA have 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.

X. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR 1271

Biologics, Communicable diseases, Drugs, HIV/AIDS, Human cells, tissues, and cellular and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

42 CFR 121

Healthcare, Hospitals, Reporting and recordkeeping requirements.

■ Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Administrator, Health Resources and Services Administration, 21 CFR part 1271 and 42 CFR part 121 are amended as follows:

21 CFR Chapter I

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 1. The authority citation for 21 CFR part 1271 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 263a, 264, 271.

■ 2. Section 1271.3 is amended by adding paragraph (d)(8) to read as follows:

§ 1271.3 How does FDA define important terms in this part?

* * * * *

(d) * * *

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

42 CFR Chapter I

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

■ 3. The authority citation for 42 CFR part 121 continues to read as follows:

Authority: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); and sections 1102, 1106, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh).

■ 4. Section 121.2 is amended by adding a sentence at the end of the definition of ''Organ'' to read as follows::

§ 121.2 Definitions.

* * * * *

Organ * * * Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled ''For use in organ transplantation only.''

* * * * *

■ 5. Section 121.7 is amended by redesignating paragraph (e) as paragraph (f) and by adding paragraph (e) to read as follows:

§ 121.7 Identification of organ recipient.

* * * * *

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

Dated: April 10, 2006.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Dated: February 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy, Food and Drug Administration.

[FR Doc. 06–4369 Filed 5–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 202

[DoD–2006–OS–0077; 0790–AG31]

Department of Defense Restoration Advisory Boards

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of Defense (DoD) is promulgating the Restoration Advisory Board (RAB) rule regarding the scope, characteristics, composition, funding, establishment, operation, adjournment, and dissolution of RABs. This rule implements the requirement established in 10 U.S.C. 2705(d)(2)(A), which requires the Secretary of Defense to prescribe regulation regarding RABs. This rule is based on DoD's current policies for establishing and operating RABs, as well as the Department's experience over the past ten years.

DATES: This rule is effective May 12, 2006.

FOR FURTHER INFORMATION CONTACT: For specific questions or to request an opportunity to review the docket for this rulemaking, please contact Ms. Patricia Ferrebee, Office of the Deputy Under Secretary of Defense (Installations & Environment), 703–571–9060. This final rule, along with relevant background information, is available on the World-Wide Web at the Defense Environmental Network and Information eXchange Web site at *https://www.denix.osd.mil/rabrule.*

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Authority

This rule is being finalized under the authority of Section 2705 of Title 10, United States Code (U.S.C.).

II. Background

The Department of Defense (DoD) published the Restoration Advisory Board (RAB) rule in the **Federal Register** as a proposed rule on January 28, 2005 (70 FR 4061) in 32 U.S. Code of Federal Regulations (CFR) Part 202. The public comment period for the proposed rule ended March 29, 2005. Thirty-four commenters submitted comments on the proposed rule. The preamble to this final rule consists mainly of an explanation of the Department's responses to these comments. Therefore, both this preamble and the preamble to the proposed rule should be reviewed should a question arise as to the meaning or intent of the final rule. Unless directly contradicted or superseded by this preamble to the rule or by the rule, the preamble to the proposed rule reflects DoD's intent for the rule.

The preamble to the final rule provides a discussion of each proposed rule section on which comments were received. Revisions to the proposed rule that are simply editorial or that do not reflect substantive changes are not addressed in this preamble. All comments the Department received are presented in a ''Response to Comments'' document, which has been placed in the docket for this rulemaking.

DoD recognizes the importance of public involvement at military installations. For the purposes of this rule, the term installation means operating and closing DoD installations and formerly used defense sites (FUDS) that reacquire environmental restoration. DoD has developed community involvement policies to ensure that local communities are provided the opportunity as early as possible to obtain information about, and provide input to, the decisions regarding environmental restoration activities at military installations. It is DoD policy to provide the public with the ability to participate in these activities through the establishment of RABs, among other public involvement opportunities.

Based on statutory and regulatory requirements for community