

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total Hours					419,225

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 29, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-17406 Filed 7-10-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1534]

#### Agency Information Collection Activities; Announcement of OMB Approval; Year 2001 Updates of a National Survey of Prescription Drug Information Provided to Patients

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Year 2001 Updates of a National Survey of Prescription Drug Information Provided to Patients" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 6, 2000 (65 FR 59849), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0279. The approval expires on June 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: July 3, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-17253 Filed 7-10-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0263]

#### Heinold Feeds, Inc.; Withdrawal of Approval of New Animal Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) listed below. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of the NADAs because the products are no longer manufactured or marketed. **DATES:** Withdrawal of approval is effective July 23, 2001.

**FOR FURTHER INFORMATION CONTACT:** Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

**SUPPLEMENTARY INFORMATION:** Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347, has requested that FDA withdraw approval of NADA 95-628 for Tylosin® Antibiotic Premix and NADA 127-506 for Tylan® Sulfa-G Premixes because the products are no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 95-628 and 127-506, and all supplements and amendments thereto, is hereby withdrawn, effective July 23, 2001.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA

is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: July 2, 2001.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 01-17408 Filed 7-10-01; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-1341]

#### "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier" dated July 2001. The guidance document is intended to assist manufacturers of Source Plasma who wish to participate in the Center for Biologics Evaluation and Research (CBER) pilot program for Red Blood Cell immunization. The pilot program would allow a licensed manufacturer of Source Plasma to self-certify conformance to specific criteria and recommendations described by CBER in the guidance document in lieu of submission of a detailed biologics license application supplement filing. The guidance document announced in this notice finalizes the draft guidance document entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier" dated June 2000.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the

Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier" dated July 2001. The guidance document is intended to assist those applicants who qualify and wish to participate in CBER's Red Blood Cells Immunization Program (RBCIP) pilot. A manufacturer is qualified if it: (1) Holds an unsuspended and unrevoked biologics license for Source Plasma, (2) seeks to supplement the license to include an RBCIP, (3) plans to use already thawed and deglycerolized Immunogen Red Blood Cells (IRBC) from an outside supplier, and (4) has identified an outside supplier of IRBC who holds an unsuspended and unrevoked biologics license for Source Plasma that already includes CBER's authorization for an RBCIP.

In the **Federal Register** of July 18, 2000 (65 FR 44537), FDA announced the availability of a draft guidance document entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier" dated June 2000. FDA received no comments from the public on this draft guidance document. The guidance document announced in this notice finalizes the draft guidance document with minor editorial changes.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on a pilot program specific to the immunization of Source Plasma donors using IRBC obtained from an outside supplier, either from an outside manufacturer, under a contractual agreement, or from an outside facility under the same managerial control as the applicant facility. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

##### **II. Comments**

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 27, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-17254 Filed 7-10-01; 8:45 am]

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. 99D-2213]

##### **Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance document entitled "Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors" dated July 2001. The guidance document provides guidance to blood establishments on when to invalidate donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety. The guidance document announced in this notice finalizes the draft guidance document entitled "Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors" dated September 1999.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Revised