TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

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

[1] 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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4160–01–S

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