prepared statements will be given the opportunity to speak, but the Panel may not be able to accommodate all such requests. Any individual who would like to attend the hearing at Lackland Air Force Base must present at any of its gates on the hearing date: (1) A picture identification (such as a driver's license), and (2) proof of automobile insurance, if driving a vehicle. The gate located closest to the Lackland Gateway Club is the Luke East Gate on Military Drive, which intersects U.S. Highway 90. More detailed guidance on hearing procedures will be provided to presenters by E-mail in advance of the hearings. Any interested party may submit full statements for inclusion in the hearing records by 5:30 p.m. on August 22. The hearings will be transcribed.

Further information, including hearing transcripts and copies of statements by all presenters, will be available on the GAO website, *www.gao.gov*, by clicking on ''Commercial Activities Panel.''

Jack L. Brock, Jr.,

Managing Director, Acquisition and Sourcing Management, General Accounting Office.

[FR Doc. 01–17270 Filed 7–10–01; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0267]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on certain general medical device labeling provisions.

DATES: Submit written or electronic comments on the collection of information by September 10, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Labeling—21 CFR Parts 800, 801, and 809

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Certain of the provisions of section 502 of the act require that manufacturers, importers, and distributors of medical devices disclose information about themselves or their devices on the labels or labeling of the devices. Section 502(b) of the act requires that, if the device is in a package, the label must contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents. Section 502(f) of the act provides that the labeling of a device must contain adequate directions for use. FDA may grant an exemption from the adequate directions for use requirement, if FDA determines that adequate directions for use are not necessary for the protection of the public health.

FDA regulations in parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require manufacturers, importers, and distributors of medical devices to disclose to health professionals and consumers specific information about themselves or their devices on the label or labeling of their devices. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations in parts 800, 801, and 809 derive from the requirements of section 502 of the act, which provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular, or fails to contain adequate directions for use.

Sections 800.10(a)(3) and 800.12(c) require that the label of contact lens cleaning solutions contain a prominent statement alerting consumers to the tamper-resistant feature required by § 800.12.

Section 800.10(b)(2) requires that the labeling of liquid ophthalmic preparations packed in multiple-dose containers include information as to duration of use and necessary warnings to afford adequate protection from contamination during use.

Section 801.1 requires that the label of a device in package form contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that the labeling of devices include directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines intended use. Where necessary, the labeling should include: (1) Statements of all conditions, purposes, or uses for which the device is intended, unless the device is a prescription device subject to the requirements of

§ 801.109; (2) quantity of dose; (3) frequency of administration or application; (4) duration of administration or application; (5) time of administration, e.g., in relation to meals, onset of symptoms, etc.; (6) route of method or application; and (7) preparation for use.

Section 801.61 requires that the principal display panel of an over-the-counter device in package form must include a statement of the identity of the device. The statement of the identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label of an over-the-counter device in package form must include a declaration of the net quantity of contents. The label must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices. A prescription device is defined as a device which, because of its potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to use the device and, therefore, for which adequate directions for use by a lay person cannot be developed.

Labeling must include information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose which it is intended, including all purposes for which it is advertised or represented.

Section 801.110 establishes a labeling requirement for a prescription device delivered to the ultimate purchaser or user upon the prescription of a licensed practitioner. The device must be accompanied by labeling bearing the name and address of the licensed practitioner and the directions for use and cautionary statements, if any, contained in the order.

Section 801.405 establishes labeling requirements for articles intended for lay use in repairing and refitting dentures.

Section 809.10(a) and (b) provide labeling requirements for in vitro diagnostic products including the label and a package insert.

These estimates are based on FDA's registration and listing database for medical device establishments, agency communications with industry, and FDA's knowledge of and experience with device labeling. We have not estimated a burden for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, we have not estimated a burden for that information that is disclosed to third parties as a usual and customary part of a medical device manufacturer, distributor, or importer's normal business activities. We do not include any burden for time that is spent designing labels to improve the format or presentation.

From its registration and listing databases, FDA has determined that there are approximately 20,000 registered device establishments. About 2,000 of these are distributing over-the-counter devices. About 18,000 are distributing prescription devices. About 1,700 establishments are distributing in vitro diagnostic products.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.10(a)(3) and 800.12(c)	4	10	40	1	40
800.10(b)(2)	4	10	40	40	1,600
801.1	20,000	3.5	70,000	0.1	7,000
801.5	2,000	3.5	7,000	22.35	156,450
801.61	1,000	3.5	3,500	1	3,500
801.62	200	5	1,000	1	1,000
801.109	18,000	3.5	63,000	17.77	1,119,510
801.110	10,000	50	500,000	0.25	125,000
801.405(b)	40	1	40	4	160
801.420(c)	40	5	200	40	8,000
801.421(b)	10,000	160	1,600,000	0.30	480,000
801.421(c)	10,000	5	49,500	0.17	8,500
801.435	45	1	45	96	4,320
809.10(a) and (b)	1,700	6	10,200	80	816,000
809.10(d)	300	2	600	40	24,000
809.10(e)	300	25	7,500	1	7,500
809.10(f)	20	1	20	100	2,000
809.30(d)	300	25	7,500	1	7,500
Total Hours					2,772,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.410(f)	30	769,000	23,070,000	0.0008	19,225
801.421(d)	10,000	160	1,600,000	0.25	400,000

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