Lane, rm. 16B–31, Rockville, MD 20857, 301–827–1471.

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 listed below.

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.

Customer/Partner Service Surveys

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research relating to regulated articles and to conduct educational and public information programs relating to responsibilities of the agency. Executive Order 12862, entitled ''Setting Customer Service Standards,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys and focus groups to implement Executive Order 12862. Participation in the surveys and focus groups will be voluntary. This request covers customer service surveys of regulated entities, such as food processors; cosmetic, drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers partner surveys of State and local governments.

FDA will use the information gathered through surveys and focus groups to identify strengths and weaknesses in service to customers and partners and to make improvements. The surveys and focus groups will assess timeliness, appropriateness, accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA projects 12 customer service and 12 partner service surveys per year, with a sample of between 500 and 2,000 customers each. After the first year, some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/partner service and developing long-term data. Also, FDA plans to conduct 12 focus groups per year (6 for customers and 6 for partners), primarily for the purpose of gaining input into the design of service surveys.

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

ESTIMATED ANNUAL REPORTING BURDEN

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Mail/telephone surveys	36,000	1	.25	9,000
Focus Groups	120	1	1.5	180
Total	36,120	1	.255	9,180

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

These estimates are based on experience with other surveys FDA has conducted.

Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18525 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0226]

Elanco Animal Health; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Elanco Animal Health. The NADA provides for the use of tylosin soluble powder in animal drinking water. The sponsor requested the withdrawal of approval of the NADA because the animal drug product is no longer being marketed.

EFFECTIVE DATE: July 25, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 13–029 Tylan® Plus Vitamins (tylosin), which provides for the use of tylosin in swine drinking water for control and treatment of swine dysentery. Elanco Animal Health requested withdrawal of approval of the NADA because the animal drug product is no longer being marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and 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 NADA 13–029 and all supplements and amendments thereto is hereby withdrawn, effective July 25, 1997.

Dated: June 20, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–18456 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0268]

Draft Guidance for Industry; Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics.'' This draft guidance was prepared by FDA's Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The draft guidance discusses information on container closure systems used in packaging drugs that manufacturers should provide to CDER in meeting regulatory requirements for new drug applications (NDA's), abbreviated new drug applications (ANDA's), investigational new drug applications (IND's), abbreviated antibiotic applications (AADA's), and supplements to these applications, and to CBER in meeting requirements for biologics license applications (BLA's) and product license applications (PLA's). The draft guidance, when completed, will supersede the agency's ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics,'' issued February 1987. The agency requests comments on the draft guidance.

DATE: Written comments by September 15, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan C. Schroeder, Center for Drug Evaluation and Research (HFD–570), 5600 Fishers Lane, Rockville MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for Packaging of Human Drugs and Biologics.'' The guidance discusses information on container closure systems used in packaging drugs that manufacturers should provide to CDER and CBER in meeting regulatory requirements for initial applications, amendments, and supplements.

The Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA to establish standards for drug product packaging, including containers and closures. According to section 501(a)(3) of the act (21 U.S.C. 351(a)(3)), a drug is deemed to be adulterated if its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health * * *. Under section 505(b)(1)(D) of the act (21 U.S.C. 355(b)(1)(D)), an application for approval to market a new drug must include ''a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.'' FDA's regulations on current good manufacturing practices for the control of drug product containers and closures are set forth in subpart E of part 211 (21 CFR part 211). In particular, § 211.94 states that finished drug manufacturers must establish and follow ''[s]tandards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties * * * for drug product containers and closures.''

In February 1987, FDA issued a ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics.'' The guideline was intended to provide drug manufacturers with guidance on preparing information on the fabrication and quality of containers and container components for use in the submission of NDA's, ANDA's, IND's, or PLA's.

The draft ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for Packaging of Human Drugs and Biologics'' revises and updates the February 1987 guideline to reflect innovations in drug product container closure systems that have occurred in the past decade. In addition, the document provides more extensive guidance on qualification and quality control of packaging components used with drug products having particular dosage forms and routes of administration, including the following: Inhalation drug products, drug products for injection and ophthalmic drug products, liquid-based oral and topical drug products and topical delivery systems, solid oral dosage forms and powders for reconstitution, and other dosage forms. The draft guidance also addresses post-approval packaging changes, Type III drug master files, and bulk containers. The draft guidance, when completed, will supersede the 1987 guideline.

This draft guidance represents the agency's current thinking on submitting information in drug applications on container closure systems used in packaging human drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. A regulated entity may adopt an alternative approach to submitting information on container closure systems if such approach satisfies the applicable statutory and regulatory requirements.

Interested persons may, on or before September 15, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this draft guidance is available via Internet using the World Wide Web (WWW) at http://www.fda.gov/cder/guidance.htm.