(3) use of visual perspectives or techniques that misrepresent product [illegible]racteristics or aspects of [illegible]nonstrations.

[illegible]art IX of the order prohibits [illegible]spondents from creating, producing, selling or disseminating any advertisement that misrepresents that it is not a paid advertisement. Part IX also requires respondents to include, in any advertisement 15 minutes or longer, a disclosure indicating that the program is a paid advertisement. The order sets out the specific language for the disclosure and the times it must appear.

The order, in Part X, also requires respondents to pay $275,000 in consumer redress.

Parts XI–XV of the order contain provisions relating to compliance with the order.

The purpose of this analysis is to facilitate public comments on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

Doc. 93–17136 Filed 7–19–93; 8:45

BILLING CODE 6750–01–M

[illegible]PARTMENT OF HEALTH AND [illegible]IAN SERVICES

[illegible]d and Drug Administration

[illegible]ocket No. 93N–0239]

Animal Drug Export; MOXIDEC® (Moxidectin) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that American Cyanamid Co. has filed an application requesting approval for export to Japan of MOXIDEC® (Moxidectin) Tablets for use as a canine anthelmintic.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of nonfood animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: [illegible]ory S. Gates, Center for Veterinary [illegible]licine (HFV–110), Food and Drug [illegible]ministration, 7500 Standish Pl., [illegible]ockville, MD 20855, 301–295–8617.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review an application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that American Cyanamid Co., Agricultural Research Division, P.O. Box 400, Princeton, NJ 08543–0400, has filed an application requesting approval for export to Japan of the animal drug MOXIDEC® (Moxidectin) Tablets. The drug is used for prevention of canine heartworm disease.

The application was received and filed in the Center for Veterinary Medicine on May 28, 1993, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 30, 1993, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: July 12, 1993.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 93–17087 Filed 7–19–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0222]

Guidance Documents on Refusal to File New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidance documents concerning refusals to file new drug applications (NDA's), product license applications (PLA's), and establishment license applications (ELA's). The first guidance document entitled "New Drug Evaluation Guidance Document: Refusal to File" describes the circumstances under which the Center for Drug Evaluation and Research (CDER) will refuse to file NDA's that are facially deficient under the agency's regulations. The second guidance document entitled "Center for Biologics Evaluation and Research (CBER): Refusal to File (RTF) Guidance for Product License Applications (PLA's) and Establishment License Applications (ELA's)" describes the circumstances under which CBER will not accept a license application for filing. These guidance documents are in use in both CDER and CBER and are meant to promote efficiency, timeliness, and consistency in the agency's reviews of NDA's, PLA's, and ELA's.

DATES: Written comments by September 20, 1993.

ADDRESSES: Submit written requests for single copies of the guidance documents to the Office of Small Business, Scientific and Trade Affairs (HF–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1 12420 Parklawn Dr., Rockville, 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The guidance documents and comments are available for public examination in the Dockets Management Branch between 9 a.m. 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION

Persons needing information on the CDER guidance document should contact: Jane Axelrad, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2894. Persons needing information on the CBER guidance document should

contact: Michael Beatrice, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–496–3556.

SUPPLEMENTARY INFORMATION: FDA believes that the practice of submitting an incomplete or inadequate application and later "repairing" it during an extended review period is inefficient and that it wastes agency resources. Accepting an application that is obviously in need of extensive modification is unfair to those sponsors who have fulfilled their scientific and legal obligations by submitting a complete and fully analyzed application. An incomplete application, submitted prematurely, may delay review of a more complete application from another sponsor. Moreover, an incomplete or inadequate application that needs several cycles of FDA response and sponsor repair excessively consumes FDA and industry resources. The incomplete or inadequate application generates more "start-up time" as well as extra reviews, letters, and meetings.

FDA's regulations describe certain circumstances in which the agency may refuse to file an application (§§ 314.101 and 601.2 (21 CFR 314.101 and 601.2)). Both CDER and CBER have decided that a more detailed explanation of how they are implementing these regulations can improve substantially the efficiency of their review processes. Because of the differences in the CDER and CBER regulations and programs, separate but similar guidance documents have been developed.

CDER's regulations describe in some detail when CDER will refuse to file an application. Section 314.101(d)(3), states: "The application or abbreviated application is incomplete because it does not on its face contain information required under section 505(b) and section 505(j), or section 507 of the act and § 314.50 or § 314.94." CDER's guidance document clarifies the manner in which FDA is applying § 314.101(d)(3). RTF decisions may also be made under other provisions of § 314.101 (i.e., those provisions included in § 314.101(d)(1), (d)(2), (d)(4) through (d)(9), and (e)), but are not specifically addressed in the guidance document.

CBER's regulations list general categories of information required to be submitted in any establishment or product license application. CBER's guidance document describes how CBER makes threshold determinations that the information submitted to support licensure is sufficiently complete to permit a substantive and meaningful review.

Both guidance documents recognize that although RTF is not a final determination and is often an early opportunity for the sponsor to develop a reviewable and potentially approvable application, it is a significant step that delays, at least for a time, full review of the application. Therefore, it is important that RTF be reserved for applications with defects that make the application plainly inadequate or nonreviewable plainly without major repair, or that make review unreasonably difficult. Both guidance documents indicate that in general the deficiencies leading to RTF should be objective and straightforward, not matters of subtle judgment, and should not be quickly reparable.

FDA has concluded that explaining it applies its regulations in making RTF decisions will substantially improve the quality of NDA, PLA, and ELA submissions and the efficiency of the new drug evaluation and biological product review processes.

To assess the scientific and procedural quality of RTF decisions, CDER recently announced the formation of a committee to review RTF decisions (58 FR 28983, May 18, 1993). The CDER RTF review committee consists of senior CDER and CBER officials, and FDA's Chief Mediator and Ombudsman. The review committee will examine selected CDER RTF's to assess, among other things: The consistency of RTF practices throughout new drug evaluation offices and divisions, the need for additional guidance on application content and format, and the need to modify CDER's RTF policies. CBER will develop a similar oversight mechanism in which CDER will be represented. The presence of CBER representatives on CDER's review committee and the participation of CDER representatives in CBER's oversight process will help to ensure consistent application of RTF principles throughout the Centers.

Interested persons may, on or before September 20, 1993, submit to the Dockets Management Branch (address above) written comments on the guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 14, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–17088 Filed 7–16–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0202]

Guidance on Alternatives to Lot Release for Licensed Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is describing its current practices governing lot release for licensed biological products. This document describes the information that should be submitted by manufacturers of licensed biological products and the approach that FDA's Center for Biologics Evaluation and Research (CBER) is using when evaluating alternatives to lot release. CBER's decisions in this regard are based on a continued assurance that the safety, purity, and potency of the product will be maintained. This action is being taken in response to requests for guidance on alternatives to lot release. FDA invites comments on this guidance statement.

DATES: Submit written comments by September 20, 1993.

ADDRESSES: Submit written comments and information to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, 20857. Submit product license application amendments requesting alternatives to lot release and sample submission requirements to the director of the application division within the office having primary jurisdiction over the product (e.g., Office of Therapeutics, Office of Vaccines, or Office of Blood), Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448.

FOR FURTHER INFORMATION CONTACT: JoAnn M. Minor, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–295–9074.

SUPPLEMENTARY INFORMATION: FDA is describing its current procedure for considering requests from manufacturers regarding alternatives to the submission of samples and of protocols that show results of applicable tests (commonly called "lot release") as set forth in 21 CFR 610.2. This notice