

the telephone number and contact person(s) for each such producer.

(j) *Additional information.* The petition shall include:

(1) The names of all U.S. importers and all producers in China of the subject merchandise known to petitioner, and the street address, telephone and fax number, and primary contact person(s) for each such importer and producer in China;

(2) A detailed description of each product for which the petitioner requests the Commission to seek pricing information in its questionnaires, and an explanation of why the petitioner believes the Commission should collect pricing information for each such product;

(3) For each domestic producer represented by petitioner, the company names of its 10 largest purchasers, and the street address, telephone number, and primary contact person(s) for each such purchaser;

(4) For each allegation of lost sales and/or lost revenues, supporting information with regard to each such alleged loss, including the name of the company represented by petitioner that lost the sale or revenue, the name of the company that captured the sale or whose competition resulted in lost revenue (including company street address, company contact person, and telephone and fax numbers for each contact person), the date and total value of the lost sale or lost revenue, and the total quantity of product involved (by weight or number of units).

(k) *Petitions under section 421(o).*

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■ 2. Amend part 206 by adding § 206.44a to read as follows:

§ 206.44a Special rules for conducting investigations under section 421(b) of the Trade Act.

(a) *Service of the petition.* (1)(i) The Secretary shall promptly notify a petitioner when, before the establishment of a service list under § 206.17(a)(4) of this part, he or she approves an application under § 206.17(a)(2) of this part pursuant to § 206.47. When practicable, this notification shall be made by facsimile transmission. The petitioner shall then serve a copy of the petition, including all confidential business information, on the approved lead authorized applicants in accord with § 206.17(f) within 2 calendar days of the time notification is made by the Secretary.

(ii) Upon establishment and issuance of the service list, the petitioner shall serve the lead authorized applicants enumerated on the list established by the Secretary pursuant to § 206.17(a)(4)

that have not been served pursuant to paragraph (a)(1)(i) of this section within 2 calendar days of the establishment and issuance of the Secretary's list.

(2) As the Secretary adds new authorized applicants to the service list described in paragraph (a)(1) of this section, the Secretary shall notify the petitioner and issue an amended list, and the petitioner shall serve new lead authorized applicants with a copy of the petition in the same manner as under paragraph (a)(1)(i) of this section.

(3) The petitioner shall serve a copy of the non-confidential version of the petition on those persons enumerated on the list established by the Secretary pursuant to § 201.11(d) of this chapter within 2 calendar days of the establishment and issuance of the Secretary's list, and on any additional persons within 2 calendar days of receiving notification from the Secretary of an amended list.

(4) The petitioner shall attest service of the petition by filing a certificate of service with the Commission.

(b) *Comment on information.* The parties shall have an opportunity to file comments on any information disclosed to them after they have filed their posthearing brief. Comments shall concern only such information, and shall not exceed 15 pages of textual material, double-spaced and on single-sided stationery measuring 8½ x 11 inches. A comment may address the accuracy, reliability, or probative value of such information by reference to information elsewhere in the record, in which case the comment shall identify where in the record such information is found. New factual information and arguments based on that information shall be disregarded. The date on which such comments must be filed will be specified by the Commission when it specifies the time that information will be disclosed. The record shall close on the date such comments are due, except with respect to changes in bracketing of confidential business information permitted by § 206.8(c) of this part.

Issued: November 13, 2003.

By Order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the veterinary prescription use of dexamethasone injectable solution in dogs, cats, cattle, and horses.

DATES: This rule is effective November 19, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-312 that provides for use of DEXIUM (dexamethasone) Solution for the treatment of primary bovine ketosis and as an anti-inflammatory agent in dogs, cats, cattle, and horses. Cross Vetpharm Group's DEXIUM Solution is approved as a generic copy of Schering-Plough Animal Health's AZIUM Solution 2 milligrams, approved under NADA 12-559. The ANADA is approved as of October 20, 2003, and the regulations are amended in 21 CFR 522.540 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment