albendazole solution for treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats. These data are contained in PMF 5582.

Under 21 CFR 25.15(d) and 25.33(d)(4), sponsors of NADA's and supplemental NADA's for drugs in minor species, including wildlife and endangered species, are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement when the drug has been approved for use in another or the same species where similar animal management practices are used. The categorical exclusion applies unless, as defined in § 25.21 (21 CFR 25.21), extraordinary circumstances exist which indicate that the proposed action may significantly affect the quality of the human environment. Therefore, based upon information available, FDA agrees that when the application is submitted, the applicant may claim a categorical exclusion under § 25.33(d)(4) provided that the applicant can state that to the best of the applicant's knowledge, as in § 25.21, no extraordinary circumstances exist. It is assumed that the applicant has made a reasonable effort to determine that no extraordinary circumstances exist.

Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF 5582 to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: Data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; data concerning manufacturing methods, facilities, and controls; and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Gillian A. Comyn (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: March 20, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–9571 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0497]

Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the notice requesting the submission of proposed product standards for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cells. The notice was published in the **Federal Register** of January 20, 1998 (63 FR 2985). FDA is taking this action in response to a request for an extension and to allow interested parties additional time for review and to submit comments on proposed product standards.

DATES: Submit written comments by July 17, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 20, 1998 (63 FR 2985), FDA published a notice requesting proposed product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use. Interested persons were given until January 20, 2000, to submit written comments. On January 18, 2000, a comment requesting that the agency extend the comment period was submitted to the docket. The comment noted that comprehensive standards that cover all aspects of cord blood banking have been drafted. However, additional editing and final review is required before submission to the docket. FDA finds it appropriate to reopen the comment period to permit interested persons additional time to submit proposed product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use. Therefore the agency is reopening the comment period for an additional 90 days, until July 17, 2000, to allow the public more time to submit proposed product standards.

Interested persons may submit to the Dockets Management Branch (address above) written comments on proposing product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use by July 17, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 10, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–9582 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79N–0113; DESI 2847]

Pediatric Parenteral Multivitamin Products; Drug Efficacy Study Implementation; Announcement of Marketing Conditions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 26, 2000 (65 FR 4253). The document announced the conditions for marketing pediatric parenteral multivitamin drug products for the indications for which they are