

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01D-0107]

**Guidance for Industry: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#121) entitled "Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims." The guidance provides advice to industry about the process that the Center for Veterinary Medicine (CVM) plans to use to grant expedited review status (ERS) for applications for new animal drugs intended to reduce human pathogens in food-producing animals.

**DATES:** Submit written comments on the guidance at any time.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, e-mail: svaughn@cvm.fda.gov.

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**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a guidance for industry entitled "Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims." The guidance advises industry about the process that CVM intends to use to grant expedited review status for applications for new animal drugs designed to reduce human pathogens in food-producing animals and to thereby potentially decrease the incidence of human illness. Specifically, it provides procedures for requesting and criteria for granting expedited review status for new animal drug applications and investigational new animal drug applications for new animal drugs that will have human pathogen reduction claims on their labels. The guidance reflects the agency's current thinking on these procedures and criteria.

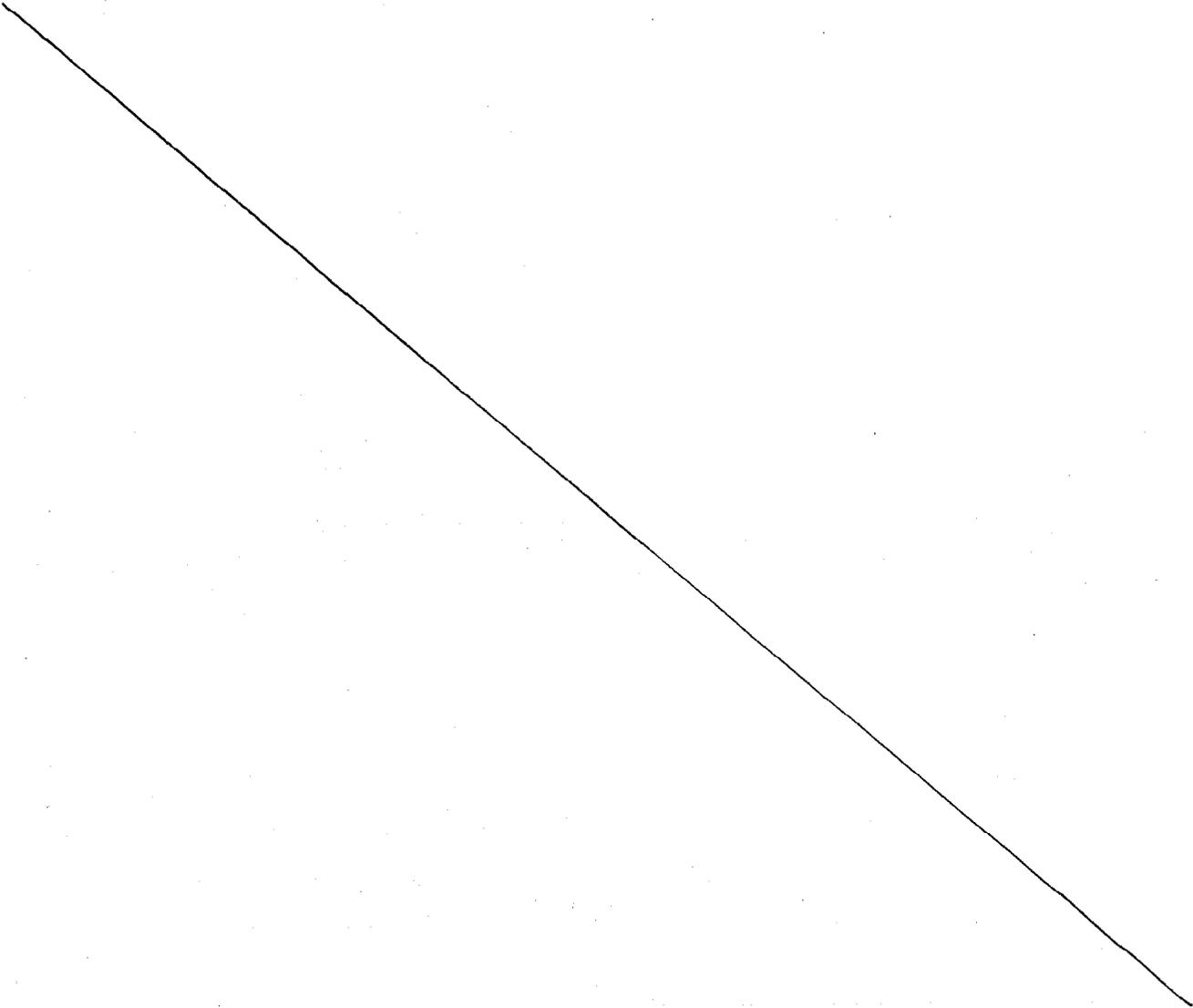
This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). FDA has determined that obtaining public participation prior to issuance of this guidance is not appropriate. The goal of this guidance is to allow products to be approved more quickly if they potentially offer important advances in reducing human pathogens in food animals, and thereby may result in a decrease of the incidence of human illness, and are supported by appropriate data. Implementing the guidance immediately, prior to receiving public comment, will further advance this goal. The concern for public health is supported by Congress. The committee reports for the fiscal year 2001 agriculture appropriations bills (H. Rept. 106-619 and S. Rept. 106-288) state that: "In view of the significant public health benefits of competitive exclusion products, the FDA should review new animal drug applications for these products on an expedited basis."

While FDA will immediately implement this guidance, the agency is inviting public comment and will revise the document as appropriate. The guidance represents the agency's current thinking on the procedures for requesting and criteria for granting ERS for applications for new animal drugs designed to reduce human pathogens in food-producing animals. It does not create or confer

any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance at any time. 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 brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Copies of this guidance document may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>.

Dated: March 6, 2001  
March 6, 2001.

Ann M. Witt

Ann M. Witt,  
Acting Associate Commissioner for Policy.

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Joyce Strong for  
Demoni Oliver

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