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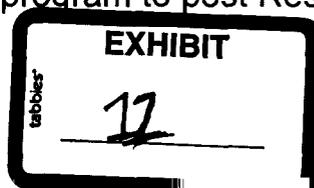
FDA's Electronic Freedom of Information Reading Room - Warning Letters and Responses

Terry Fredeking

This page is designed to simplify the search for Warning Letters and Responses. Choose any of the seven search categories and view or download the Warning Letter or Response. Use the Warning Letters and Responses Search Form for advanced searching. All Warning Letters and Responses are available in PDF format. The ADOBE ACROBAT Reader is required to review PDF files. Click on the ADOBE icon and download the free reader. Warning Letters posted after June 25, 2001 and Responses posted after September 22, 2003 are also available in HTML format.

Matters described in FDA Warning Letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter. If you wish to obtain available additional information on the current status of an issue in a particular Warning Letter on this website, please contact the Agency or the recipient of the letter directly. Inquiries to FDA should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at <http://www.fda.gov/opacom/backgrounders/foiahand.html>.

The Food and Drug Administration cannot assure the accuracy of information submitted to the Agency without a complete review of the submitted materials and resolution of the issues discussed therein. To make certain information available to the public, the agency has undertaken a pilot program to post Responses to



Warning Letters before evaluating the documents and resolving the issues. The Responses are redacted to the extent permitted by the Freedom of Information Act.

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U.S. Food and Drug Administration

Results of Warning Letters Search

Company Name	Date Warning Letter Issued	Issuing Office	Subject	File	Response Posted
North Texas IRB	4/14/03	Center for Biologics Evaluation and Research	Institutional Review Board	[PDF] [HTML]	No

 Warning Letters

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