

FINDING OF NO SIGNIFICANT IMPACT
FOR

GRAS Affirmation Petition 9G0260, submitted by Novo Nordisk Bioindustrials, Inc., to affirm the GRAS status of cellulase from *Trichoderma longibrachiatum* (formerly *T. reesei*) in foods.

The Environmental Impact Section, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment prepared using the format described in 21 CFR 25.31a(a), an expanded market volume projection in a letter dated September 17, 1991, and on the following analysis:

1. The scope of the petition was expanded to include uses beyond those considered in the environmental assessment (EA). The petitioner estimated that the revised scope would lead to a projected market of 13,806 metric tons (letter of September 17, 1991). However, we conclude that the analysis and conclusions presented in the original EA remain accurate, even considering the expanded market.
2. FDA considered the potential for introductions of epichlorohydrin (ECH) into the environment as a result of approval of this petition. ECH is present as a contaminant in the flocculating agent used in the preparation of the enzyme product. Based on information on the expected contaminant levels and the manufacturing process presented in the petition, FDA concludes that no significant introductions of ECH will result from approval of this petition.

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Approved by: Michael C. Hoffmann Date: 26 Nov 91
for Buzz L. Hoffmann, Ph.D., Chief
Environmental Impact Section