

Dated: February 29, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G-0035]

Sankyo Co., Ltd.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 6G0420) proposing to affirm that the use of dextranase enzyme preparation derived from *Chaetomium gracile* is generally recognized as safe (GRAS) in cane and beet sugar processing.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 14, 1996 (61 FR 5787), FDA announced that a petition (GRASP 6G0420) had been filed by Solvay Enzymes, Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001 (now, Sankyo Co., Ltd., No. 7-12, Ginza 2-chome, Chuo-ku, Tokyo 104-8113, Japan). This petition proposed that the use of dextranase enzyme preparation derived from *Chaetomium gracile* in cane and beet sugar processing be affirmed as GRAS. Sankyo has now

withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 1, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0046]

Quarterly List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing an update of all guidance documents issued and withdrawn since we compiled the annual comprehensive list of guidance documents that published on June 10, 1999. FDA committed to publishing quarterly updates in its February 1997 "Good Guidance Practices" (GGP's) final rule, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued since the annual comprehensive list was compiled.

DATES: General comments on this list and on agency guidance documents are welcome 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. For

information on where to obtain single copies of guidance documents listed here, see the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT:

LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its "Good Guidance Practices" (GGP's), which set forth our policies and procedures for developing, issuing, and using guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of our guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, we committed to publishing an annual comprehensive list of guidance documents and quarterly **Federal Register** notices that list all guidance documents that were issued and withdrawn during that quarter, including "Level 2" guidance documents. The following list of guidance documents represents all guidances that we issued or withdrew since we published the annual comprehensive list on June 10, 1999 (64 FR 31228). The guidance documents are organized by the issuing center or office within FDA, and are further grouped by the intended users or relevant regulatory activities. Dates provided in the following list refer to the date of the guidance was issued or, where applicable, the last date the document was revised. We provided document numbers where available.