

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Food and Drug Administration

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Memorandum

Date:

November 21, 2002

From:

Division of Standards and Labeling Regulations, Office of Nutritional Products,

Labeling and Dietary Supplements, HFS-822

Subject:

75-Day Premarket Notification of New Dietary Ingredients

To:

Dockets Management Branch, HFA-305

New Dietary Ingredient:

Ganoderma lucidum Spore Powder (Shell-

Broken)

Firm:

Herbs Generation International Ltd.

Date Received by FDA:

April 29, 2002

90-Day Date:

July 28, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Catalina Ferre-Hockensmith

Attachments

955-03/6

RPT129