

Food and Drug
Administration
Rockville MD 20857

Mr. Neil Edwards
Associate Director,
Worldwide Regulatory Affairs
Parexel International
The Quays, 101 - 105 Oxford Road
Uxbridge, Middlesex UB8 1LZ
United Kingdom

AUG 23 2004

RE: Docket No. 2004-0346

Dear Mr. Edwards:

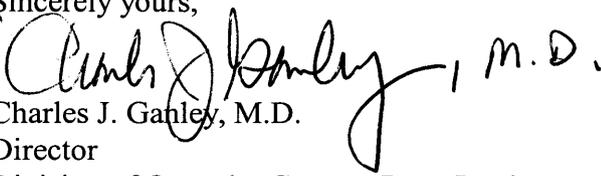
This letter is in response to your e-mail message of May 9, 2004, requesting confidentiality of certain information contained in the Time and Extent Application (TEA) for *Saccharomyces boulardii* as an anti-diarrheal agent. After reviewing your request, we agree to redact all of the information that you identified as confidential. FDA considers this information to be confidential commercial information according to 5 U.S.C. 552 (b)(4) and 21 CFR 20.61(b) and (c) (§ 20.61(b) and (c)). Thus, FDA will redact the following country-specific sales information:

- original TEA: pp. 19 through 26
- original TEA: attachment 3 (pp. 121 through 130)
- original TEA: attachment 4 (pp. 132 through 142)
- TEA addendum: pp. 5 through 9

FDA also agrees with your request to demonstrate extent of marketing by geographic regions (i.e., continents) rather than by individual countries. Section 330.14(c)(2) stipulates that marketing information be provided for each country, and your TEA provided this information. However, FDA agrees with your assertion that, in the interests of maintaining confidentiality, country-specific sales information should not be made publicly available. Therefore, prior to putting your TEA on public display, FDA agrees to replace the redacted country-specific data with the summary table you provided. This table shows estimated OTC sales on the three continents that include the selected countries.

All sections of the TEA that we have agreed to redact will be removed from the submission prior to it being placed on public display at the Division of Dockets Management. If you have any questions or comments, please contact Dr. Michael L. Koenig of this division at 301-827-2222.

Sincerely yours,


Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research