



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Office of Policy, Planning, and Legislation HF-11
5600 Fishers Lane
Rockville, MD 20857

July 22, 2002

Peter Barton Hutt, Esq.
Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401

Re: Docket No. 98N-0583

Dear Mr. Hutt:

This letter is in regard to your Petition for Reconsideration and Stay of Action, dated June 17, 2002, in which you requested both reconsideration and a stay of two provisions in the final export notification and recordkeeping rule. The final rule appeared in the *Federal Register* on December 19, 2001 (66 Fed. Reg. 65429), was originally supposed to become effective on March 19, 2002, but had its effective date extended to June 19, 2002 (67 Fed. Reg. 34387 (May 14, 2002)).

On June 20, 2002, the Food and Drug Administration (FDA) informed you that the agency would exercise enforcement discretion and not generally take enforcement action regarding:

- (1) the last sentence of 21 CFR 1.101(b), "The records shall be made available to the Food and Drug Administration, upon request, during an inspection for review and copying by FDA," with respect to foods and cosmetics exported under or subject to section 801(e)(1) of the Federal Food, Drug and Cosmetic Act (the Act) only; and
- (2) 21 CFR 1.101(b)(2).

The enforcement discretion period was to expire on July 19, 2002 and pertained solely to the provisions (identified above) in the final rule. We advised you that affected parties must continue to comply with the statutory requirements for exports under sections 801(e) and 802 of the Act.

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This letter advises you that FDA has decided to continue to exercise enforcement discretion regarding the last sentence of 21 CFR 1.101(b), as it pertains to foods and cosmetics

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exported under or subject to section 801(e)(1) of the Act, and also the provision regarding a letter from an appropriate foreign government agency or a notarized certification in 21 CFR 1.101(b)(2). We reiterate that affected parties must continue to comply with the statutory requirements for exports under sections 801(e) and 802 of the Act. The enforcement discretion period will continue while we consider whether any revisions to 21 CFR 1.101(b) and 1.101(b)(2) are necessary. We are currently evaluating whether to issue an Advanced Notice of Proposed Rulemaking to obtain public comment on questions related to the issues raised in your petition.

Sincerely,



Margaret M. Dotzel
Associate Commissioner for Policy