



JUL 16 2004

Food and Drug Administration
Rockville MD 20857

Ms. Nancy L. Buc
Ms. Kate C. Beardsley
Buc & Beardsley
919 Eighteenth Street, N.W.
Washington, D.C. 20006-5503

Dear Ms. Buc and Ms. Beardsley:

This letter is an interim response to your May 18, 2004, complaint and request for correction pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000), hereinafter referred to as the "Federal Data Quality Act," concerning the Food and Drug Administration's (FDA's) Consumer Campaign on Safe Use of OTC Pain Products. Your complaint was submitted on behalf of your client, McNeil Consumer & Specialty Products. Dr. Lester M. Crawford, Acting Commissioner of Food and Drugs, has referred this matter to me for a response.

FDA's data quality guidance, which is part of the Department of Health and Human Services *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, September 30, 2002, states that FDA will respond to a complaint under the Federal Data Quality Act within 60 days, either by issuing a decision or by informing you that more time is required to respond to the complaint, explaining why, and providing you with an estimated decision date.

We have not yet completed our response to your complaint because of other agency priorities and the need to coordinate agency review of the response. We anticipate that a response will be provided within 60 days.

If you have any questions, you may contact Jane Axelrad at 301-594-5400.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Galson".

Steven Galson, M.D., M.P.H.
Acting Director, Center for Drug Evaluation and
Research

CC: FDA's Office of the Ombudsman