



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

May 25, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Via e-mail and mail

Re: Over-the-Counter Drug Products
Public Hearing: Docket No. 00N-1256

To Whom It May Concern:

The Food and Drug Administration (FDA) announced a public hearing about the agency's approach to regulating over-the-counter (OTC) drug products, with the intent of soliciting information from, and the views of, interested persons. In that announcement, FDA stated its intention "to elicit comment on general issues regarding the status of OTC drug products, including criteria the agency should consider in rendering decisions on OTC availability of drugs, the classes of products, if any, that are not currently available OTC that should or should not be available OTC, how FDA can be assured that consumers understand the issues relating to OTC availability of drug products, how rational treatment decisions are affected by coexisting prescription and OTC therapies for a given disease, whether the current structure for marketing OTC products in the United States is adequate, and FDA's role in switching products from prescription to OTC status."

CHPA is the 119-year-old trade organization representing nonprescription drugs and dietary supplements, including over 200 members across the manufacturing, distributing, supply, research testing, and advertising sectors of the self-care industry. CHPA and its members have a direct interest in this matter before the agency and over the years have provided commentary to the agency on virtually all aspects of OTC medicines and their regulation. CHPA is the principal trade industry group representing manufacturers of nonprescription medicines. Our members represent over 95% by sales of the over-the-counter drug marketplace.

CHPA requests 45 minutes on the agenda at the Part 15 hearing on June 28-29, 2000, to address the issues raised in the FDA meeting announcement, as summarized above. We ask for this amount of time because we are the sole trade group representing the entire nonprescription drug industry, and the matters raised in the Federal Register announcement are of great importance to our membership and the future of OTC research and development.

CHPA's comments will focus on three areas pertaining to overall policy matters -- legal issues relating to OTC availability and approval, and specific technical and process issues relating to Rx-to-OTC switch. Three individuals will provide our oral remarks at the hearing. They are employees of the Association:

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Michael D. Maves, M.D., M.B.A. – President
Eve E. Bachrach, Esq. – Senior Vice President, General Counsel and Secretary
R. William Soller, Ph.D. – Senior Vice President and Director of Science &
Technology

If the agency decides to organize the meeting by “question category” rather than by groups of participants, we ask to be included in each of the question categories. On this point, because CHPA is the only trade group representing the OTC drug industry, we think it advantageous for FDA to have an overall industry viewpoint entered in each area discussed at the meeting.

I look forward to your response. Should you have questions, or wish clarification or additional material from CHPA, please do not hesitate to call me or my assistant,
Ms. Judith Quaempts.

Sincerely yours,

(Signature appears on mailed copy.)

R. William Soller, Ph.D.
Senior Vice President and
Director of Science and Technology

WS/jkq:Switch/FDAJuneMtg/RequestforTimeLetter

Butler, Jennie C

From: Quaempts, Judith [JQuaempts@CHPA-info.org]
Sent: Thursday, May 25, 2000 12:02 PM
To: 'FDADockets@oc.fda.gov'
Subject: June28-29 Public Meeting



requestforTimeLetter.d

cc

Attached is a letter to Dockets requesting time on the agenda for the June 28-29 meeting on over the counter drug products. A hard copy is being mailed today.

<<requestforTimeLetter.doc>>