



1620 I Street, NW • Suite 800 • Washington, DC 20006
202-833-9070 • Fax: 202-833-9612 • Email: info@gphaonline.org

9403 '01 JUN 26 10:07

June 22, 2001

Documents Management Branch
[HFA-305]
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 00N-1269
Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics;
Requirements for Prescription Drug Product Labels

Dear Sir or Madam:

The Generic Pharmaceutical Association (GPhA) is pleased to have the opportunity to comment on the Proposed Rule regarding "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels" which was published in the Federal Register of Friday, December 22, 2000. (On March 20, 2000, the comment period was extended to June 22, 2001.)

GPhA is comprised of the manufacturers and distributors of generic medicines, as well as bulk API manufacturers and suppliers. Our dosage form manufacturer members will be directly impacted by implementation of this regulation, when finalized. We, therefore, submit the following comments for your consideration in the revision of this proposed rule.

We support the Agency's efforts to improve the content and format of prescription drug labeling to make important drug safety information more readily accessible. Because the FD&C Act [21 USC 505(j)(2)(v)] and the regulations [21 CFR § 314.94(a)(8)(iv)] require ANDA drug labeling to be the same as the labeling approved for the reference listed drug (except for changes required because of differences approved under a suitability petition or because the drug product and the reference listed drug are produced or distributed by different manufacturers), we will restrict our comments to format and implementation issues.

While we support this initiative, GPhA is greatly concerned that the increased length and complexity of the proposed new prescription drug labeling format, combined with the requirement for a minimum of eight point type size, will create logistical difficulties in obtaining paper of appropriate size for printing the package inserts, as well as attaching the information to each drug package. The impact would be somewhat less onerous if a minimum of six-point type was permitted, as the Agency permits for OTC drugs [21 CFR § 201.66(d)(2)].

As another alternative, GPhA supports the Pharmaceutical Research and Manufacturers of America's Paperless Labeling initiative, and hopes the Agency will consider implementing the new prescription drug labeling format concurrently with acceptance of electronic dissemination of prescribing information as an alternate to paper package inserts, via a uniform effective date.

00N-1269

C58

Lastly, GPhA is concerned that NDA holders might use the implementation provisions of the proposed rule as a vehicle to block generic competition. An NDA holder whose marketing exclusivity for the original indication(s) is about to expire might obtain approval, and three years' marketing exclusivity, for a new indication, and reformat their labeling accordingly. We urge the Agency to address this issue in any Final Rule issuing from the Proposed Rule, in a manner that will permit ANDA applicants to base their labeling on the previously-approved labeling of the listed drug, until such time as the NDA holder's exclusivity for the new indication has expired.

GPhA represents over 140 generic firms, including drug makers, suppliers of bulk active ingredients, contract research organizations, distributors and consulting firms. Together, member companies supply more than 92 percent of the total generic prescriptions filled each year and 40 percent of the total brand and generic scripts dispensed annually.

These comments were also entered electronically via the FDA Dockets Management website.

Sincerely

A handwritten signature in black ink, appearing to read 'S. Bende', written over a horizontal line.

Steve Bende, Ph.D.

Vice President

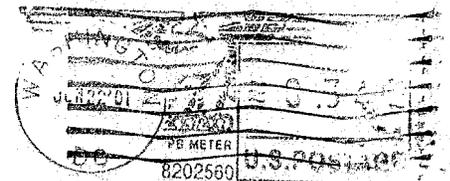
Science, Professional and Regulatory Affairs

Generic Pharmaceutical Association



Generic Pharmaceutical Association

1620 I Street, NW, Suite 800
Washington, DC 20006



Documents Management Branch
[HFA-305]
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

20857+0001

