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April 4, 2003

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 95N-0304: Dietary Supplements Containing Ephedrine Alkaloids

Dear Sir or Madam:

On behalf of our client, Metabolife International, Inc. ("Metabolife"), I am writing to document FDA's written confirmation that it will accept comments for the above-mentioned docket until April 7, 2003.

As the agency is aware, in its February 28, 2003 press release, "HHS Acts to Reduce Risks of Dietary Supplements Containing Ephedra," FDA indicated that comments may be submitted to the above-mentioned docket until April 7, 2003. The applicable Federal Register notice, however, identified a different deadline.

Due to these contradictory statements, I contacted the agency and obtained written confirmation (signed, on FDA letterhead, dated March 27, 2003) that comments will be accepted until April 7, 2003. I have attached this signed letter, and hereby submit it to the docket.

I appreciate the agency's willingness to confirm the April 7, 2003 deadline, and note that in reliance upon FDA's representations, Metabolife expects to submit its comments on April 7.

Sincerely,

Paul D. Rubin

Attachment

95N-0304

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 27, 2003

Dietary Supplements Containing Ephedrine Alkaloids

Food and Drug Administration agrees to accept comments submitted by April 7, 2003.

The date specified in the March 5, 2003, federal register notice (volume 68, Number 43) to reopen the comment period for the proposed rule entitled "Dietary Supplements Containing Ephedrine Alkaloids" stipulates that the FDA will accept comments submitted to docket number 95N-0304 until April 4, 2003.

However, the February 28, 2003 FDA press release, "HHS Acts to Reduce Risks of Dietary Supplements Containing Ephedra" stipulates that April 7, 2003 is the last date comments will be accepted.

Therefore, FDA agrees to accept comments submitted to docket 95N-0304 that are postmarked no later than April 7, 2003.

A.T. Curry
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