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May 18, 2000

Paul D. Rubin
(202) 457-5646
prubin@pattonboggs.com

BY FAX and HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Dietary Supplements Containing Ephedrine Alkaloids [Docket No. 00N-1200]

Dear Sir or Madam:

On behalf of our client, Metabolife International Inc. ("Metabolife"), we are submitting this letter to preserve our right to submit, in the near future, more detailed comments regarding dietary supplements that contain ephedrine alkaloids – and to incorporate by reference the entire original docket dedicated to this issue [Docket No. 95N-0304] into the new docket [Docket No. 00N-1200] recently created by the agency.

In its Federal Register notice making available "new" adverse event reports allegedly associated with dietary supplements containing ephedrine alkaloids, 65 Fed.Reg. 17510 (April 3, 2000), FDA indicated that the comment period would end on May 18, 2000 (i.e. 45 days after publication). The agency established such a short time-frame despite the fact that the "new" AERs were collected over a three-year period, FDA denied the public access to the AERs for over two years, and FDA originally waited almost three years to issue its original 1997 proposed rule regarding dietary supplements that contain ephedrine alkaloids.

Based upon the extensive number of AERs referenced by the agency, and the number of agency reports included in the docket, 45 days is clearly an inadequate amount of time for regulatory industry to scientifically analyze these materials and prepare an appropriate response. Accordingly, FDA was requested to issue an extension of 180 days.

In a May 5, 2000 letter to The Honorable Dan Burton, Chairman, Committee on Government Reform, U.S. House of Representatives, signed by Melinda K. Plaisler, Associate Commissioner for Legislation at the FDA, the agency indicated that it would issue at least an additional 45 day extension – which would extend the comment period to July 3, 2000. Regulated industry has relied upon the representations contained in this letter, and continues to rely upon them, despite the fact that as of today the agency has still not issued a formal extension of the comment period.

00N-1200

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PATTON BOGGS LLP
ATTORNEYS AT LAW

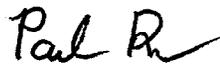
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Regulated industry continues to request an extension of 180 days in order to adequately respond to the voluminous docket created by the agency.

This letter is therefore intended to memorialize our reliance upon FDA's representation that an extension would be granted, and to preserve our right to submit comments in the near future (subsequent to the original deadline of May 18, 2000).

Finally, the agency has created a new docket [Docket No. 00N-1200] to address the "new" AERs and reports recently issued by the agency. Due to the fact that this new docket constitutes a continuation of the issues previously addressed by the agency with regard to dietary supplement products that contain ephedrine alkaloids, we hereby incorporate by reference the entire original docket dedicated to this issue [Docket No. 95N-0304] into the new docket.

Respectfully submitted,



Paul D. Rubin