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2011 FEB 11 A 10:47

February 10, 2011

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VIA ELECTRONIC FILING (www.regulations.gov)
AND UPS NEXT DAY AIR

Division of Dockets Management
HFA–305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Request for Extension of Time to Comment
Docket Nos. FDA–2000–P–0102, FDA–2000–P–0133, and FDA–2006–P–0033

Dear Madam/Sir:

We write to request an extension of the comment period regarding the U.S. Food and Drug Administration's ("FDA") recent proposed rule that: (1) would amend 21 C.F.R. § 101.83, which governs health claims and phytosterols, and (2) indicated FDA's intention to abandon its enforcement discretion based on its 2003 Letter of Enforcement Discretion ("2003 Letter").[1]

In particular, under the proposed rule, only dietary supplements containing esterified phytosterols are eligible for the health claim, which is a significant departure from the agency's position in its 2003 Letter. FDA invited public submission of additional data that demonstrate the cholesterol-lowering efficacy of nonesterified, or free, phytosterols consumed as ingredients in dietary supplements, and stated that the agency would consider additional information before making a final determination on this issue. FDA also requested data to provide a justification for inclusion/exclusion of a specific dietary supplement formulation using USP standards.

Presently, the comment period is scheduled to end on February 22, 2011. We respectfully request that this period be extended sixty (60) days, or until April 23, 2011, to ensure that all interested parties have sufficient time to submit the information and data requested by the agency.

As FDA notes, the proposed rule would prohibit marketers of dietary supplement products containing free phytosterols from making coronary heart disease health claims, which would have a significant adverse impact on numerous manufacturers who produce these products. In addition, removing these products from the marketplace without sufficient scientific justification

[1] 75 Fed. Reg. 76,526 (Dec. 8, 2010).

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comprehensive assessment prepared by independent experts with relevant expertise in the field. Extending the comment period would allow interested members of the public, patients, clinicians and businesses the time necessary to provide the agency with a thorough review of available materials and information on this important issue.

Given the substantial impact upon all of these interested parties and consumers, we respectfully request that FDA extend the date by which comments are due until April 23, 2011.

Respectfully,

Michelle Jackson

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WS 11.0.15 LP2844 12.0A 01/2011