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BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION (FDA)

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

FDA's INFORMATION COLLECTION ACTIVITIES, SUBMISSION FOR OFFICE OF MANAGEMENT AND BUDGET REVIEW and COMMENT REQUEST regarding PETITIONS TO REQUEST AN EXEMPTION FROM 100 PERCENT IDENTITY TESTING OF DIETARY INGREDIENTS under CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS (21 CFR 111)

Submitted to:
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Prefatory Remarks

The Food and Drug Administration (FDA or the Agency) issued a Federal Register notice on November 28, 2014 announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) in relation to 21 CFR § 111.75(a)(1)(ii), Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients.[1] The November 28, 2014 notice also provided information on the how to submit comments on this information collection.

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

AHPA's members are engaged in the commerce of herbs and herbal products, including herbal dietary supplements. In the course of this commerce many AHPA members are engaged in activities that are covered by 21 CFR § 111. AHPA's members therefore have an interest in the subject of this information collection. These comments are therefore submitted on behalf of AHPA's members.

An exemption to 100 percent identity testing should be retained under cGMP regulation

FDA issued 21 CFR § 111.75(a)(1)(ii) as an Interim Final Rule on June 25, 2007.[2] In the preamble to that rule FDA stated:

> "…we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing."

[1] 79 FR 70876.
[2] 72 FR 34959.

This same view is repeated by the agency in the November 28, 2014 notice that is the subject of the present comments. The Agency also identified, both in the preamble to the June 2007 rule and in the November 2014 notice, the genesis of § 111.75(a)(1)(ii) as follows:

> "To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1) an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 and the Agency grants such exemption."

AHPA agrees that a system of less than 100 percent identity testing can result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. AHPA therefore strongly supports the maintenance of a regulatory option to 100 percent identity testing.

FDA should clarify whether any petitions under 21 CFR 111.75(a)(1)(ii) have been submitted to date

The November 28, 2014 notice states FDA has not "In the last 3 years" received "any ***new*** petitions to request an exemption from 100 percent identity testing of dietary ingredients" [emphasis added]. AHPA notes that the Agency has made the same statement in earlier information collection notices issued in relation to this same regulation on several other dates, including one issued on July 20, 2010, less than three years after the first date on which FDA would have accepted such a petition.[3] This statement was also repeated in relevant information collection notices issued on September 30, 2010 and November 14, 2013. To the best of AHPA's knowledge, these represent all of the Federal Register notices issued to date by FDA on information collection for this regulation in which the Agency reported on its receipt of, or in fact absence of any receipt of petitions under this regulation.

In issuing this regulation in June 2007 FDA provided some rationale for its decision to add this exemption to § 111.75(a), as follows:

[3] In the preamble to the Interim Final Rule FDA stated it would "consider a manufacturer's request for an exemption from the testing required by § 111.75(a)(1) of the CGMP final rule once the compliance date for that manufacturer … passes." 72 FR 34960. The earliest such date was June 25, 2008.

> "Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements." 72 FR 34960.
>
> "The exemption from 100 percent identity testing of dietary ingredients gives dietary supplement manufacturers, who choose to request an alternative testing regime and obtain permission from FDA for an exemption, potential relief from the burden of having to test the identity of every lot of dietary ingredients, while not reducing the quality of such ingredients used in the manufacture of finished products." 72 FR 34962.

It is AHPA's understanding, however, that FDA has never received a petition under § 111.75(a)(1)(ii). If AHPA's understanding is accurate, AHPA requests that in all future notices FDA include a statement as to the number of petitions received under § 111.75(a)(1)(ii) since its establishment as an interim final rule on June 25, 2007.

If in fact there have been no petitions under § 111.75(a)(1)(ii) received to date it may be that FDA's stated goal "of providing flexibility in the CGMP requirement" has not been met and that dietary supplement manufacturers may not have been provided with the "potential relief" mentioned in this rulemaking.

The estimated annual reporting burden is speculative

AHPA notes that FDA states in the November 28, 2014 notice that it has relied on its experience with petition processes generally to estimate that it will take a requestor about 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition.

AHPA has no information either to support this estimate or to provide any other estimate. As noted above, however, it is AHPA understands that FDA has not received any petitions under the subject rule since it was promulgated in 2007. Until such time as one or more petition is prepared and submitted to FDA in relation to this specific rule, however, any such estimate must be considered to be largely speculative.

Conclusions

AHPA appreciates the opportunity to comment on this notice of FDA's information collection activity. Given the absence of any apparent use to date of the subject regulation it is difficult to know with any certainty the actual associated reporting burden. In spite of this non-use to date, however, AHPA continues to believe that it is important to maintain this possible exemption to 100 percent identity testing in order to provide regulatory flexibility and encourage supplement companies to identify and implement systems of less than 100 percent identity testing that would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing.

AHPA staff and counsel will make themselves available at any mutually convenient time to address any of the topics addressed herein. Please feel free to contact me if clarification or further discussion is needed on the issues raised in these comments.

Respectfully submitted,

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