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REQUEST FOR EXTENSION OF COMMENT PERIOD

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs

71 Fed. Reg. 51276 (August 29, 2006)
Docket No. 2005N-0403
RIN 0910-AA49

October 12, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Request for Extension of Comment Period (Docket No. 2005N-0403 / RIN 0910-AA49)

Dockets Management Branch:

The Consumer Healthcare Products Association (CHPA) submits this request under 21 C.F.R. §§ 10.35 and 10.40(b)(3), requesting that the Commissioner of Food and Drugs extend for an additional sixty (60) days the comment period on the proposed rule, “Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs” (Docket No. 2005N-0403 / RIN 0910-AA49). *71 Federal Register* 51276 (August 29, 2006).

A. Decision involved

On August 29, 2006, the U.S. Food and Drug Administration (FDA) published a proposed rule on the “Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that

Consumer Healthcare
Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org

are Regulated Under a Biologics License Application, and Animal Drugs” (Docket No. 2005N-0403 / RIN 0910-AA49). 71 *Federal Register* 51276 (August 29, 2006). The proposed rule seeks to “reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, human drugs that are biological products, . . . and animal drugs.” Written or electronic comments on the proposed rule must be submitted by November 27, 2006.

B. Action Requested

Under 21 C.F.R. §§ 10.35 and 10.40(b)(3), CHPA requests that the Commissioner of Food and Drugs extend the comment period on the above-referenced proposed rule for an additional sixty (60) days. If granted, written or electronic comments on the proposed rule would be due by January 26, 2007.

C. Statement of Grounds

CHPA, founded in 1881, is the national trade association representing manufacturers and distributors of nonprescription (or over-the-counter) medicines and dietary supplements. As such, we have an interest in the subject-matter of the proposed rule.

CHPA has examined the proposed rule and discussed it with member companies. It is clear that the detail of the proposed rule and the numerous complex scenarios it may create for entities along the supply chain, the need to examine carefully the information contained in the proposed rule, and the impact of the proposed rule on CHPA member companies, large and small, will require more time than that allotted by the agency to submit a response.

The proposed rule will affect all pharmaceutical manufacturers, but some of these changes may be felt more acutely by the over-the-counter (OTC) drug industry. The impact may depend on whether the product is marketed pursuant to an approved new drug application (NDA) or under an OTC monograph, or it may depend on whether the product is already marketed or first reaches the market after the effective date of the new regulations.

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The importance of comments is further highlighted by FDA's specific requests for comment within the proposed rule itself. FDA requests comment on a plethora of topics, such as the burden that may result from requiring that manufacturers affirmatively certify when updating their registration and listing information that no changes have occurred. FDA also seeks comment on, among other topics, which specific registration and listing information should be available for public disclosure. Many of these issues will require extended industry discussion and review. CHPA will need more time to obtain and sort out opinions and responses from member companies.

In addition, there may be topics not specifically requested for comment by FDA in the proposed rule on which CHPA may wish to comment. For example, we are concerned about substantial changes the proposed rule may have on the monograph system in general, and (in particular) the effect of agency assignment of a National Drug Code (NDC) number to manufacturers of OTC monograph drugs, which reach the market without prior approval from FDA.

Finally, the public interest will not be disserved by allowing additional time requested for comment upon the proposed rule. Allowing an additional sixty (60) days will provide time for the affected industry to submit more focused and detailed comments. We note that CHPA intends to meet with its members to encourage and assure input and to endeavor to reach consensus on issues of concern.

Respectfully submitted,



Paul J. Larsen, Esq.
Associate General Counsel & Secretary
Consumer Healthcare Products Association
900 19th Street, NW
Suite 700
Washington, DC 20006
Phone: (202) 429-9260
E-mail: plarsen@chpa-info.org