



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

Docket No. 2005N-0403 / RIN 0910-AA49

October 13, 2006

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

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

Dear Sir or Madam:

L. Perrigo Company (Perrigo) 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).

Written or electronic comments on the proposed rule currently must be submitted by November 27, 2006. If granted, written or electronic comments would be due by January 26, 2007.

Introduction

Perrigo is the nation's largest private label manufacturer of over-the-counter (OTC) drug products, supplying products to numerous mass merchandisers, chain drugstores and supermarkets. Perrigo markets OTC drug products subject to OTC monographs as well as approved ANDAs and NDAs. Perrigo also manufactures and distributes prescription drugs.

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Perrigo submits an average of 450 drug listings (Form 2657 and 2658s) and 100 de-listings per year. In order to more efficiently manage this large volume, Perrigo submits listings 4 times per year (quarterly) pursuant to a request from FDA. Currently, Perrigo has approximately 7000 active drug listings.

Statement of Grounds

The proposed rule, when finalized, will have a profound impact on all manufacturers, but will most acutely affect private label manufacturers and distributors. Perrigo currently distributes its products to 45 private label retail chains (e.g. Walgreen's, CVS). In developing comments related to this proposed rule, Perrigo must address the impact to Perrigo and its systems as well as the impact to its retail customers.

Perrigo anticipates that this proposed rule will require drastic changes to many internal systems including those related to labeling development. Additional time is required in order to fully evaluate these changes and quantify the economic burden associated with the need to implement such process changes.

Summary

Due to the complexity of Perrigo's business, the large number of private label retail customers, the large volume of annual and current listings in conjunction with the complexity of the proposed rule, it is necessary for Perrigo to request a sixty (60) day extension to the comment period.

This extension will allow Perrigo to fully understand and evaluate the proposed changes, evaluate the economic impact to the business and to provide detailed and meaningful comments to FDA

Respectfully Submitted;

A handwritten signature in cursive script that reads 'Heidi Horn'.

Heidi Horn
Associate Director, Regulatory Affairs
L. Perrigo Company