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March 19, 2013

BY HAND DELIVERY

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

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PETITION FOR STAY OF ACTION

Dear Sir or Madam:

Pursuant to 21 C.F.R. § 10.35, Hyman, Phelps & McNamara, P.C. submits this Petition on behalf of a client ("Company")[1] requesting that the Commissioner of Food and Drugs stay certain decisions identified in a March 15, 2013, letter from the Acting Director of Center for Drug Evaluation and Research's ("CDER's") Office of Manufacturing and Product Quality within the Office of Compliance denying the Company's request for reconsideration of certain issues pertaining to a Warning Letter issued on February 21, 2013 (erroneously dated 2012). Specifically, we request that the Commissioner stay publication of the Warning Letter on the Food and Drug Administration's ("FDA's") website until (1) an appeal of the March 15, 2013 decision has been exhausted and (2) the Agency has considered and responded to redactions to the Warning Letter requested by the Company to protect its confidential commercial information and/or trade secrets pursuant to 21 C.F.R. §§ 20.61, 20.47.

[1] Understanding that this docket is public, the Company declines to identify itself further, although, if there is any doubt as to the Company's identity, the undersigned will further provide such information in response to a phone call.

FDA-2013-P-0337

2013-2005

DSA

A. DECISIONS INVOLVED

The Warning Letter issued to the Company on February 21, 2013, contained observations and information pertaining to a specific drug ("Drug") that has never been commercialized in the United States. On February 25, 2013, the Company requested that the Agency reconsider certain items related to the Warning Letter, including the presence of any observations relating to the Drug. On March 15, 2013, the Acting Director of CDER's Office of Manufacturing and Product Quality within the Office of Compliance denied the Company's request for removal of information about the Drug from the Warning Letter and stated that the Agency intends to publish the Warning Letter on FDA's website after the Agency reviews the Warning Letter "for any information that needs to be redacted before public disclosure." As the Drug has never been commercialized in the United States, the Company believes observations regarding the Drug were inappropriately included in the Warning Letter. The Company disagrees with the Agency's decision to retain information about the Drug in the Warning Letter and is appealing this decision pursuant to 21 C.F.R. § 10.75.

In addition, in response to the Agency's March 15, 2013, decision, the Company requested yesterday, March 18, 2013, specific redactions to the Warning Letter to prevent disclosures of confidential commercial information and/or trade secrets, as defined at 18 U.S.C. § 1832 *et seq.* and 21 C.F.R. § 20.61. The Company is awaiting the Agency's response to its request for redactions to the Warning Letter.

B. ACTION REQUESTED

We request that FDA grant this Petition for Stay of Action and refrain from posting the Warning Letter on FDA's public website until (1) the appeals process regarding the content of the Warning Letter has been exhausted and (2) the Agency has considered and responded to the redactions to the Warning Letter requested by the Company on March 18, 2013.

C. STATEMENT OF GROUNDS

1. Irreparable Injury to the Company

The Company will suffer irreparable injury absent the requested stay. Publishing the Warning Letter prior to the conclusion of the appeals process would disclose findings related to the Drug that the Company has requested be removed from the Warning Letter.

Disclosure of this information is especially inappropriate where, as here, the product is not commercialized for sale in the United States. Public disclosure of this information prior to the exhaustion of the appeals process would cause irreparable harm to the Company at the hands of its competitors, in addition to causing irreparable reputational harm among the Company's patients, customers, and physicians. Should FDA refuse to stay the Warning Letter's publication before the appeals process is exhausted, the decision to publish the letter constitutes a final agency action warranting judicial intervention. *See Darby v. Cisneros*, 509 U.S. 137, 148 (1993) (citing Senate Judiciary Committee report emphasizing that, "unless the administrative decision meanwhile is inoperative," the effect of requiring administrative exhaustion would be to "subject the party to agency action . . . without recourse").

The Company has also contacted the Agency to request that information regarding the Drug be redacted from the Warning Letter. Public disclosure of this information prior to the Agency's consideration and decision would cause irreparable harm to the Company at the hands of its competitors, in addition to causing irreparable reputational harm among the Company's patients, customers, and physicians. Moreover, the Company is in a better position to determine in the first instance which of its information is confidential commercial and/or trade secret information than FDA is and does not accept the March 15, 2013, letter's review for potential redactions as sufficient to protect the Company's interests. This is consistent with the intent of the Agency's regulations governing the Freedom of Information Act ("FOIA"), which provides companies the ability to protect certain confidential information from public disclosure prior to the disclosure of certain documents to the public. 21 C.F.R. § 20.47. Indeed, should the Agency and the party disagree as to confidential disclosures, the Agency is required to provide the party five days advance notice before the disclosure, enabling the party to seek relief from the courts to block such disclosure. 21 C.F.R. § 20.48. Thus, FDA's own regulations recognize the potential harm to a company of the publication of confidential commercial and/or trade secret information.

2. <u>The Company's Case is Meritorious and is Being Pursued in Good Faith</u>

a. The Company's Case is Meritorious

As set forth in the Company's February 25, 2013, request for reconsideration of the Warning Letter, and March 18, 2013, response to the Warning Letter, the Drug should never have been the subject of an FDA Warning Letter, and publication of findings related

to that drug prior to the conclusion of an appeals process would cause irreparable harm to the Company.

Further, the Company has requested redactions to the Warning Letter pertaining to the Drug on the grounds that the information is protected confidential commercial information and/or trade secret information. Publication of the Warning Letter before the Agency has considered and decided upon the Company's requested redactions would cause harm to the Company by its competitors and among its patients, physicians, and customers.

b. The Company's Case is Being Pursued in Good Faith

The Company has expeditiously responded to all Agency communications, and has cooperated with the Agency since the issuance of the Warning Letter, including the expeditious reply to the Agency's March 15, 2013, letter, and the filing of the instant petition. Further, any and all other relief as may be necessary in this case shall be pursued with all due haste.

3. Sound Public Policy Reasons Support Issuance of a Stay

Publishing the Warning Letter prior to the formal conclusion of the appeals process would effectively nullify any outcome received in the appeals process, where, as here, an appeal is sought to prevent certain public disclosures of information. Even if an eventual appeal results in a decision favorable to the Company, such decision would have little effect, as the publication of the erroneous and harmful information would have already occurred, and caused harm and damage to the Company. It is poor public policy for the Agency to take actions that would effectively nullify the purpose of the internal appeals process.

In addition, publication of the Warning Letter where a request for redaction of confidential and/or trade secret information is pending before the Agency would similarly nullify any outcomes that may result from the Agency's eventual consideration and decision as to the Company's request for redaction. As discussed above, FDA's FOIA disclosure regulations require the Agency to provide companies the ability to protect certain confidential information from public disclosure prior to the disclosure of certain documents to the public. 21 C.F.R. § 20.47. Indeed, should the Agency and the party disagree as to confidential disclosures, the Agency is required to provide the party five days advance notice before the disclosure, enabling the party to seek relief from the courts to block such disclosure. 21 C.F.R. § 20.48. Thus, FDA's own regulations support a policy respecting an

opportunity for a party to participate in a dialog pertaining to the publication of confidential commercial and/or trade secret information.

4. Any Delay Resulting from a Stay is Not Outweighed by Public Health or Other Public Interests

The timing of the appeals process and posting of the Warning Letter is wholly within the Agency's control. The Company has timely provided the Agency with all necessary and relevant information for making its decision. Furthermore, the Company has had regular contact with the Agency relating to the Warning Letter. Indeed, as recently as March 18, 2013, the Company discussed with FDA's Office of Chief Counsel the need to protect disclosure of certain confidential commercial and/or trade secret information while the Company appeals an adverse decision to its request for reconsideration. There is no pressing need for the Warning Letter to be posted on FDA's website prior to the exhaustion of the appeals process or a determination on the Company's requested redactions to protect its confidential commercial and trade secret information.

* * *

For the foregoing reasons, we respectfully request the Commissioner of Food and Drugs grant this Petition for Stay of Action.

Respectfully submitted,

Douglas B. Farquhar

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