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VIA E-MAIL AND UPS NEXT DAY

Daniel E. Troy, Esq.
Chief Counsel
Food and Drug Administration (GCF-1)
Department of Health and Human Services
Room 6-57
5600 Fishers Lane
Rockville, MD 20817

Re: Pharmaceutical Distributors Association; Request for Stay of Action and Effective Date of Prescription Drug Marketing Act Regulations; Docket Nos. 92N-0927 and 88N-0258.

Dear Mr. Troy:

We are counsel to the Pharmaceutical Distributors Association (PDA), a trade association of state-licensed wholesale distributors of prescription drugs. We are enclosing herewith a copy of the petition that we submitted today on behalf of the PDA, joined by the American Pharmaceutical Association, the American Veterinary Distributors Association, the Food Marketing Institute, the Health Industry Distributors Association, the Healthcare Distribution Management Association, the National Association of Chain Drug Stores and the National Community Pharmacists Association to request the Commissioner of Food and Drugs to continue the stay and to suspend the effective date of those parts of the final rule (promulgated December 3, 1999) in Docket Nos. 92N-0297 and 88N-0258 which require a prescription drug pedigree to list

all prior sales back to the manufacturer (21 C.F.R. § 203.50(a)(6)) and which require a written agreement to evidence an ongoing relationship between a wholesale distributor and a manufacturer (21 C.F.R. § 203.3(u)). Those parts of the final rule are presently scheduled to go into effect on April 1, 2003.

Three prior stays of this rule have been granted (65 Fed. Reg. 25639, May 3, 2000 (to Oct. 1, 2001), 66 Fed. Reg. 12850, Mar. 1, 2001 (to April 1, 2002), and 67 Fed. Reg. 6645, Feb. 13, 2002 (to April 1, 2003)). The last two of these stays were put in place so that Congress could have the opportunity to enact legislation to amend the prescription drug pedigree requirements of the Federal Food, Drug, and Cosmetic Act. The events of September 11, 2001 and other priorities in Congress have stalled that consideration. All of this is spelled out in the PDA petition.

This letter is to request your immediate assistance to address an inequity in the application of rulemaking effective dates that we have sought, unsuccessfully, to have the FDA address since November 2000. It is an inequity that needs to be addressed to allow prescription drug wholesalers to continue in their businesses under the regulatory *status quo* that has been in place for fourteen years until April 3, 2003, the effective date that the petition seeks to have further stayed. Next, PDA asks that the FDA rule promptly on this new stay petition.

Presently, the FDA has interpreted the effective date of the rules addressed by the petition to apply to all drugs in commerce on that date. Because the rule requires certain information that was previously not required to be provided upon the sale of such drugs, the rule would apply to drugs in commerce for which the newly required information is not available and render their sale unlawful. The application of the rule to drugs already in commerce is in PDA's view wasteful, unfair and arbitrary and we seek your assistance in correcting this inequity.

First, the rule's application to drugs in commerce would render otherwise safe and effective approved drugs unlawful for no reason other than lack of paperwork. This is extraordinarily wasteful and is not justified by any public health rationale. Second, FDA's application of the effective date for this rule is inconsistent with FDA's application of effective dates to labeling and other related requirements for regulated products. Rarely, and only where a recall is ordered, has the Administration made a regulation effective in such a way that it would cause products lawfully introduced into commerce to become unlawful at a later time, and it is the usual course is for such products to remain in commerce. E.g., Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients, 67 Fed. Reg. 31125 (May 9, 2002) (Cascara sagrada and aloe) ("This applies to any OTC drug product containing any of these aloe or cascara sagrada ingredients and labeled for laxative use that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this final rule."). Finally, the application of the final rule to products in commerce is arbitrary and capricious – there is no rational basis for adversely affecting commerce in this fashion and rendering valuable and important pharmaceuticals unlawful and unsaleable.

When PDA raised this issue in November of 2000, the PDA's position that the final rule should not apply to drugs in commerce was rejected:

In its hearing testimony and in a letter submitted on November 3, 2000, the Pharmaceutical Distributors Association noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree. The association specifically stated that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm. The association specifically sought a decision by the agency that the final rule not apply to prescription drugs already in distribution as of the effective date so those drugs could be distributed. FDA acknowledges the concerns of the Pharmaceutical Distributors Association and has decided

that, in light of the uncertainty regarding how to resolve the issues involved and the possible adverse consequences that could result from implementation of the relevant provisions of the final rule, it is reasonable and appropriate to delay the effective date of Secs. 203.3(u) and 203.50 for another 6 months until April 1, 2002. Additionally, the agency has decided to delay the applicability of Sec. 203.3(q) to wholesale distribution of blood derivatives by health care entities until April 1, 2002. This delay will allow time for the agency to make its recommendations to Congress, for Congress to evaluate those recommendations, and, depending on the decisions of the agency and Congress, for a regulatory or legislative change to address the issues raised. **Although a further delay of the effective date of the relevant provisions of the final rule is not the exact relief requested by the Pharmaceutical Distributors Association, the agency believes that it accomplishes the same purpose in that it will permit unauthorized distributors to operate for an additional 6 months without concern that the drugs in their inventory may become illegal to distribute and therefore valueless.** All other provisions of the PDMA final rule became effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of Secs. 203.3(u) and [[Page 12853]] 203.50, or Sec. 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities. [65 Fed. Reg. 12850, Mar. 1, 2001].

This effective date issue that we raise with you here was not addressed at all in the most recent extension of the effective date by FDA on February 13, 2002 of this year: The effective date was simply delayed until April 1, 2003. 67 Fed. Reg. at 6646. One reason the issue may not have been addressed was that the FDA's Federal Register notice did not even acknowledge the PDA's July 12, 2001 petition for stay or its letter of July 12, 2001 to Jane Axelrad and Seth Ray requesting again that the final rule apply only to drugs first introduced into commerce after the effective date of the final rule.

It is PDA's position that the rationale set forth in the March 1, 2001 Federal Register notice is no rationale at all. It states that a stay until April 1, 2002 grants substantial relief because it allows companies to stay in business for six more months without concern about inventory status and then appears to imply that such companies can then proceed to stay in the business at their own risk until April 1, 2003. In our view

that is not a responsible response to a reasonable request to be treated similarly to other subjects of FDA rulemaking.

PDA's and its allied associations immediate request to you is for a brief letter, from you, John Taylor or some comparable official that states that FDA will apply the present final rule only to drugs first introduced into interstate commerce after April 1, 2003. If this is done, PDA members and other secondary wholesalers that are not "authorized" distributors will be able to continue their businesses to April 1, 2003. Such announced exercises of enforcement discretion are not uncommon and are even exercised with respect to safety-related regulations. E.g., Bottled Water; Technical Amendment; Confirmation of Effective Date. 66 Fed Reg. 35373 (July 1, 2001) ("FDA believes that it would be appropriate to exercise its enforcement discretion as to those bottled water products that: (1) Are already in interstate commerce before January 1, 2002; (2) do not meet the revised quality standard for the three residual disinfectants and the four types of DBPs; and (3) do not bear a statement of substandard quality-provided that such products are not adulterated. Therefore, the agency does not plan to take enforcement action against such bottled water products, provided that such products are safe.")

PDA next asks that you and your colleagues promptly address PDA's stay petition. Last year, PDA filed its stay petition on July 12, 2001 and did not receive a response until February 13, 2002 despite pleas for a prompt response because of the inventory issue. For the same reasons, we request a prompt response to the petition filed today.

We would be pleased to meet with you or anyone else at the FDA to discuss the subject of this request and the petition. The regulations for which a stay is sought will, if allowed to become final, adversely impact 6500 businesses, most of them small businesses. Because these businesses will not be able to comply with the new regulations, they will either close or be compelled to operate under a cloud of potential

regulatory and business liability. PDA and the other associations have diligently worked with Congressional staff to try to get corrective legislation passed and it is simply a fact that more time is needed to bring that process to closure.

PDA has asked that we advise you that it will seek a stay and judicial review of these regulations if there is no response to this letter or the PDA petition by December 15, 2002. We hope you will not take this as a threat. PDA's members businesses are in jeopardy from the affects of the final rule and they are required to take all necessary and appropriate steps to protect those businesses and their employees. In the past, there have been no open lines of communication with respect to the stay issue and this may have largely been related to the absence of a Commissioner. Waiting until two months before the effective date for a decision, as occurred earlier this year, simply will not work for these businesses.

Thank you for your consideration of these requests. Again, we would be pleased to meet with you at your convenience.

Sincerely yours,



Anthony L. Young
Sheldon Krantz
General Counsel
Pharmaceutical Distributors Association

Attachments

cc: Jane Axelrad
Seth Ray, Esq.