November 27, 2002

The Honorable Mark B. McClellan, M.D., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Support for the Petition for Continuation of Stay of Action; FDA Final Rule on Policies, Requirements and Procedures; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992 (64 Fed. Reg. 67,720, December 3, 1999); Docket Nos. 92N-0927 & 88 N-0258.

Dear Commissioner McClellan:

The Office of Advocacy of the U.S. Small Business Administration urges the U.S. Food and Drug Administration (FDA) to grant the Request for Stay of Action and Effective Date of two provisions in the above-referenced final rule affecting drug wholesalers.

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. The Office of Advocacy is an independent entity within the U.S. Small Business Administration (SBA), so the views expressed by the Office of Advocacy do not necessarily reflect the views of the SBA or the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires the Office of Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1] On August 13, 2002, President Bush underscored the importance of agency compliance with the RFA and the Office of Advocacy's role in giving a voice to small businesses in the rulemaking process when he signed Executive Order 13272, entitled "Proper Consideration of Small Entities in Agency Rulemaking."

Consistent with comments filed with the FDA under the previous Chief Counsel for Advocacy (February 29, 2000), we remain concerned that FDA has failed to adequately account for its impact on small business and consider less burdensome alternatives in drafting the Final Rule on Policies, Requirements and Procedures; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992 (PD Amendments).

Over 4,000 small businesses will be affected by the PD Amendments rulemaking. Considering that this represents 94% of the industry, we encourage the FDA to grant a further stay and suspend the effective date of the requirements affecting the definition of "ongoing relationship" and "authorized distributor of record."

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. § 601 et seq.) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. § 612(a).

We have attached a copy of our office's previous comment letter that offers a more detailed analysis of how the PD Amendments rule will affect small employers. Lastly, I want to offer any support necessary to assist FDA to ensure compliance with requirements under the RFA and Executive Order 13272 with regard to this rule.

Please do not hesitate to contact me at (202) 205-6533 if you have any questions regarding this letter.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

Enclosure