PDA
Parenteral Drug Association
Connecting People, Science and Regulation®

PDA Global Headquarters

Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

April 12, 2010

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Reference: [Docket No. FDA–2009–N–0247]
Transparency Task Force; Request for Comments
Ref: FR, Vol. 75, No. 48; March 12, 2010

Dear Sir/Madam,

PDA is responding to the referenced FR Notice seeking comments from interested persons on ways in which FDA can increase transparency between FDA and regulated industry. Our comments relate to area No.2 in the FR Scope statement, "The guidance development process," and to products regulated by CDER, CBER, CVM and CDRH.

Problem statement: The time period stipulated by FDA for comments on proposed rules or industry guidance published in the FR is often insufficient, thereby creating difficulties for the development of high quality and useful comments from interested persons.

Discussion: The FDA time frame for commenting varies with the norm being 60 days from the date of publication in the FR. On occasion, as is in the case of this notice, there is only 30 days. Such short timeframes are difficult for membership or constituency-based organizations such as PDA to meet. In order to prepare scientific based and consolidated comments, PDA usually reaches out to our worldwide members to (1) recruit volunteer experts on the subject, (2) organize the volunteers to review the document through a peer-based process, (3) prepare redrafts of our commentary until consensus is achieved, and (4) secure internal institutional review and approval via a formal balloting procedure involving two or more internal bodies including our governing Board of Directors. This process ensures high quality comments that are useful and helpful to FDA.

Recommendation 1: We encourage FDA to adopt a standard notice and comment time frame of 6 months, or 90 days for time sensitive issues, for rules and guidances affecting the regulated industry. This will give FDA the benefit of receiving high quality comments for use in the guidance development process, and in achieving the Agency goal of improving transparency.

Recommendation 2: We also encourage FDA to partner with member-based scientific organizations (such as PDA) to hold discussion workshops on the issues that drive new or revised rules or guidances. Similarly, after rules and guidances are finalized these same organizations can help educate stakeholders on requirements and intentions through training workshops and conferences, or by providing FDA speakers at training venues (such as the PDA Training and Research Institute) to provide more in depth understanding. These actions would increase understanding of and compliance with new requirements through educational programs serving as an adjunct to the inspection and compliance approach.

Please contact me if you have any questions.

Sincerely,

Richard Johnson
President, PDA

CC: Robert L. Dana, Richard V. Levy, Ph.D.