Plasma Protein Therapeutics Association

August 26, 2011
Reference No.: FDAA11015

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

SUBJECT: Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Recall Regulations [Docket No. FDA-2011-N-0439]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major collectors of Source Plasma and manufacturers of plasma derived products and recombinant analogues, collectively referred to as plasma protein therapies, which are used in the treatment of a number of rare diseases. The diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. The therapies include clotting-factor therapies for individuals with hemophilia A and B and other bleeding disorders; immunoglobulins to treat a complex of diseases in individuals with immune deficiencies; therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset emphysema and limits substantially life expectancy; and albumin, which is used in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

PPTA is pleased to provide these comments on the reporting requirements on FDA recalls.[1] PPTA's comments focus on

> (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.[2]

[1] *See* Federal Register / Vol. 76, No. 125 / Wednesday, June 29, 2011 / Notices, pp. 38184-86
[2] *See id.* at 38185

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In general, PPTA member data are higher than FDA's estimates of the burden of the proposed collection of information; thus, FDA's estimates appear low. For example, a member estimated the average burden per response (ABPR) for firm initiated recall and recall communications (§§ 7.46 and 7.49) is 60 (double FDA's estimate of 30)[3] and the ABPR for recall status reports and followup (§ 7.53) is 20 (double FDA's estimate of 10).[4]

However, PPTA notes that, in addition to the ABPR, data ranges are not given.[5] As stated, PPTA members manufacture plasma protein therapies, which comprise a small portion of the drug market. PPTA recognizes that "[v]ariables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause the hours per response to vary significantly"[6] and that FDA utilized "[t]he best guesstimate of average burden hours per response from previous information collection request reports."[7] However, without data ranges in FDA's estimates, PPTA is unable to assess if relatively high member data fall within the range of previously collected information or are outliers. Thus, PPTA encourages FDA to provide data ranges for industry to assess better the accuracy of the Agency's estimates.

PPTA also suggests that an electronic tool for recall reporting, or eRecall tool, if it were more effective and efficient for blood products than the manual system, could improve the recall reporting process and, thus, both enhance the quality, utility, and clarity of the information to be collected and minimize the burden of the collection of information on respondents. However, PPTA cautions that such an eRecall tool would be useful only if it were streamlined and it standardized the data requested; as such, industry should be able to give input to any developer of user requirements for an eRecall tool before implementation. In fact, for many biological product deviations (BPD), the current electronic tool for BPD reporting is more difficult to use than the manual system because of limitations in the software; thus, an ideal system would allow recall and BPD databases to communicate and to populate automatically each other with information that currently is provided multiple times to FDA. Today's reporting requirements for lookback, BPD, and recall are unduly burdensome for industry because they require redundant and often untimely reporting.

In addition, PPTA assumes that FDA's estimates include starting material (Source Plasma) recalls. However, though FDA's reporting requirements on recalls are applicable to "any … biologic intended for human use,"[8] today, the entire recall process for Source Plasma can be considered an undue burden that adds no value. The unique requirement of the lookback for blood products makes the recall process completely

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[3] *See id.*
[4] *See id.*
[5] *See id.*
[6] *See id.* at 38186
[7] *See id.*
[8] *See* 21 CFR § 7.3(f)

redundant in that all required notifications are made to the consignee, FDA, and the donor months before the Agency decides whether to classify a report as a recall. Thus, PPTA suggests that the requirements should apply only to finished goods that are consumable; such a scenario would minimize the burden of the collection of information on respondents. PPTA recommends that FDA's entire recall program, not just information collection, be reviewed to determine if the program serves the purpose originally intended to protect consumers and if the current program adds value in light of newer practices, requirements and technologies. With current budgetary constraints facing industry and government, regulatory programs must add value if maintained.

PPTA appreciates the opportunity to comment on the reporting requirements on FDA recalls and looks forward to continued work with the Agency. PPTA welcomes from FDA any questions regarding these comments and/or requests for additional information.

Thank you for your consideration.

Respectfully Submitted,

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