Plasma Protein Therapeutics Association

July 29, 2011
Reference No.: FDAA11013

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; Current Good Manufacturing Practice (CGMP) Regulations for Finished Pharmaceuticals [Docket No. FDA-2011-N-0362]

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. The therapies 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 the 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. Members are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

General comments

PPTA is pleased to provide these comments on the information collection provisions of FDA's CGMP for Finished Pharmaceuticals.[1] PPTA focuses on FDA's request for comments on "the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used … ."[2] 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 (examples below).

[1] *See* Federal Register / Vol. 76, No. 104 / Tuesday, May 31, 2011 / Notices, pp. 31342-45.
[2] *See id*. at 31342.

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However, PPTA notes that Table 1—Estimated Annual Recordkeeping Burden provides "*Average* burden per recordkeeping (in hours)"; data ranges are not given.[3] As stated, PPTA members manufacture plasma protein therapies; the therapies comprise a small portion of the drug market. Without data ranges in FDA's estimates of the burden of the proposed collection of information, PPTA is unable to assess if members' high data are factored into the Agency's averages or are outliers; PPTA encourages FDA to provide data ranges for industry to assess better the accuracy of the Agency's estimates.

Examples of low FDA estimates

211.80(d)
FDA estimates
Number of records per recordkeeper (NRPR): .25
Average burden per recordkeeping (in hours)[4] (ABPR): 6/60
PPTA experiences
NRPR: 50; ABPR: 2

211.100(b)
FDA estimates
NRPR: 3; ABPR: 2
PPTA experiences
NRPR: 5; ABPR: 13

211.105(b)
FDA estimates
NRPR: .25; ABPR: 15/60
PPTA experiences
NRPR: 8; ABPR: 2

211.122(c)
FDA estimates
NRPR: 50; ABPR: 15/60
PPTA experiences
NRPR: 100; ABPR: 2

211.165(e)
FDA estimates
NRPR: 1; ABPR: 1
PPTA experiences
NRPR: 19; ABPR 2

[3] *See id.* at 31344-45 (emphasis added) (citation omitted).
[4] "Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format '[number of minutes per response] /60.'" *Id.* at 31346.

211.180(f)
FDA estimates
NRPR: .2; ABPR: 1
PPTA experiences
NRPR: 3; ABPR: 7

211.182
FDA estimates
NRPR: 2; ABPR: 15/60
PPTA experiences
NRPR: 8; ABPR: 2

211.196
FDA estimates
NRPR: 25; ABPR: 15/60
PPTA experiences
NRPR: 33; ABPR: 3

Conclusion

PPTA appreciates the opportunity to comment on the information collection provisions of FDA's CGMP for Finished Pharmaceuticals 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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Plasma Protein Therapeutics Association