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Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Food and Drug Administration Transparency Task Force; Public Meeting [Docket No. FDA-2009-N-0247]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is pleased to provide these comments on the Food and Drug Administration's (FDA) Transparency Task Force Public Meeting [hereinafter, "Public Meeting"]. PPTA is the international trade association and standards-setting organization for the world's major producers of plasma-derived and recombinant analog therapies. Our members provide 60 percent of the world's needs for Source Plasma and protein therapies. These include clotting therapies for individuals with bleeding disorders, immunoglobulins to treat a complex of diseases in persons with immune deficiencies, therapies for individuals who have alpha-1 anti-trypsin deficiency which typically manifests as adult onset emphysema and substantially limits 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.

Introduction

PPTA welcomes the opportunity to provide comments to the Transparency Task Force [hereinafter, "Task Force"] on ways in which FDA can make useful and understandable information about FDA activities and its decision-making process. PPTA supports the agency in its effort to improve transparency as it is beneficial to both industry and the general public to understand how and why decisions are made. Overall, PPTA believes the agency communicates effectively. There is an abundance of information available on the FDA website regarding product approvals, recalls, guidance documents and regulations. Also, PPTA appreciates the efforts of the agency to attend meetings and share information with industry. It is vital that this type of dialogue continue which allows industry and regulators to fully communicate concerns and better understand decisions.

PPTA understands that this Task Force was convened to improve upon already existing processes. PPTA believes that the following recommendations will enhance policies already in place and allow for greater openness and predictability. These recommendations will improve the necessary, cooperative working relationship of industry and FDA, while increasing public confidence in agency decisions.

Recommendations

- **Establish and publish a work-plan:** Develop a work-plan that would be published in the Federal Register at the beginning of each year. This type of work-plan would outline the priorities of each center for the upcoming year. Currently, this type of work-plan is published by the European Medicines and Evaluation Agency (EMA). The more information that the agency can make available on what it will be working on the better industry will be able to understand the context for decisions, the less haphazard decisions will appear.
- **Improve the Good Guidance Practices process:** PPTA recognizes the efforts of the agency takes to publish draft guidance documents and appreciates the opportunity to comment. It is only through the Good Guidance Practices (GGPs) process of developing guidance documents that industry and others have the opportunity to comment on the agency's "current thinking". Moreover, it is critical that "current thinking" regarding new criteria be published by FDA for public and industry comment, rather than having those criteria be enforced on manufacturers on a case-by-case basis during the review process of individual Biological License Applications (BLAs). However, application of the GGPs appears to be inconsistent, specifically in the ability of the agency to finalize draft guidance documents. Guidance documents that remain in draft form do not clearly delineate the policy of the agency and lead to misinterpretation or patchwork implementation. Taking the time to clearly discern the process to finalize draft guidance documents, which includes setting an appropriate timeline for finalizing, will improve and provide more transparency to the decision-making process. PPTA recommends that the agency set a policy that if a draft guidance document cannot be finalized within 12 months it must be re-published for public comment.
- **Improve the process for publication of final regulations:** Similar to what was stated above, proposed rules remain in limbo for a number of years before being finalized. PPTA recognizes that upon publication of a final rule, all public comments are addressed; however, if the rule takes five years or more to publish the applicability of the proposed rule and comments are questionable. When a proposed rule is published and open for comment, the comments provided are based on the science and data known at that time. If it takes a number of years for the agency to publish the final rule, those comments may no longer be applicable as new data and technology are likely available. PPTA questions whether at this point the agency has provided adequate notice and comment. For example, the Proposed Rule "Safety Reporting Requirements for Human

Drug and Biological Products” was published in 2003. To date this rule has not been finalized. FDA made comments that the name of the rule had changed and that the final rule would be published soon. However, after six years how applicable is this rule if it is based on comments from six years ago and would it not be more transparent to re-propose the rule before it is finalized. PPTA recommends that FDA develop and publish a process that delineates the procedure for finalizing proposed rules. This would state that if a proposed rule is not finalized within a reasonable amount of time that the proposed rule must be re-proposed for public comment.

- **Publish agendas and background material for public meetings and advisory committees at least 30 days in advance:** Recently, materials for advisory committee meetings have not been published in a timely manner. For example, the complete meeting materials for the Blood Products Advisory Committee (BPAC) meeting held on July 20 and 21, 2009 were published 10 business days before the meeting. While that may seem like adequate time to read through materials, it is insufficient time to be fully prepared. Often times PPTA must make public statements on the issues being discussed at these meetings. As the trade association for plasma protein therapies, we must work with all of our members to develop association policy. This takes time and preparation. When materials are not available in a timely manner, it hinders our ability to fully present information at meetings. It calls into question whether advisory committee meetings provide an open forum for vetting of an issue, if adequate notice of the issue was not really provided. A short publication time does not recognize the needs of the industry or the general public. It casts a shadow of secrecy on FDA and creates the appearance of disorganization. PPTA recommends the agency establish a policy in which all materials, including background material, for meetings be published at least 30 days in advance, this would provide sufficient notice and ample time to prepare.
- **Real-time submission:** During the Prescription Drug User Fee Act (PDUFA) 4 reauthorization process, PPTA proposed that the agency develop a more predictable review process by creating a real-time submission tracking feature. Ideally, this electronic system would provide tracking information in real-time that could be accessed by the manufacturer. This type of information would make significant improvements over current predictability. This predictability would allow manufacturers to arrange for the launch of product that may have substantial improvements over the existing product. In addition, the predictability would allow a manufacturer to control inventories, schedule production runs, and plan for release of newly approved product without delay. This type of transparency and predictability will bring life-saving therapies to consumers without undue delay.
- **Improve the Freedom of Information Act (FOIA) process:** PPTA has submitted several FOIA requests with little success. Recently, PPTA received a phone call acknowledging that a significant amount of time had lapsed since a request was made. FDA questioned whether we still wanted the information.

PPTA renewed the request but still has not received the information. PPTA recommends FDA reevaluate FOIA procedures and take steps to improve the process. With that said, PPTA would like to stress that the laws and regulations that govern FOIA do not need to be change. It's the policy for reviewing and processing the requests that should be improved. It is important that as the agency evaluates ways to improve transparency, the Agency continue to assure that information that has been given special protection under FOIA, like trade secrets, remain confidential. This type of information is readily shared with FDA without fear that it will be accessible to competitors, allowing the agency the ability to fully assess a product's quality, safety, and efficacy.

Conclusion

As stated above, PPTA commends FDA's effort to improve transparency at the agency. PPTA believes that the creation of this task force was an important step in achieving a more open and predictable FDA. PPTA appreciates the opportunity to comment and looks forward to working with FDA on this important issue. Should you have questions regarding these comments or would like to discuss these issues further, please contact me at the Association. Thank you for your consideration.

If you have any questions, please contact me at the Association.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Mary Gustafson".

Mary Gustafson
Vice President, Global Regulatory Policy
Plasma Protein Therapeutics Association