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June 6, 2013

Office of Information and Regulatory Affairs
Office of Management and Budget Review (OMB)
Attn: FDA Desk Officer
Via email: oira_submission@omb.eop.gov
Electronic comments to: Docket No. FDA-2013-N-0093

Re: OMB Control Number 0910-New
Docket No. FDA-2013-N-0093: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request: Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act; 78 Fed. Reg. 26782 (May 8, 2013)

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit these comments in response to the Notice and Request for Comments entitled "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request: Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity [("NME")] New Drug Applications [("NDA")] and Original Biologics License Applications [("BLA")] in Prescription Drug User Fee Act [("the Program")]" issued by the U.S. Food and Drug Administration ("FDA").

PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested approximately $50 billion in 2012 in discovering and developing new medicines, representing the vast majority of private investment in new medicines in the United States. PhRMA member companies are committed to the development of innovative, life-saving and life-altering treatments and cures for serious and life-threatening conditions.

PhRMA supports the Program and believes it can promote greater regulatory transparency by improving communication between the FDA review team and companies, resulting in improved efficiency and effectiveness during the first cycle of review. An efficient and effective review process that allows for timely responses to FDA questions and information for sponsors can help ensure timely patient access to safe, effective, and high-quality new drugs and biologics.

PhRMA appreciates FDA's attention to fulfilling performance commitments made under PDUFA V with regards to the Program and the issuance of the proposed information collection as part of the independent interim and final assessments of the Program. PhRMA trusts that FDA will continue to seek stakeholder input as it continues to implement the Program and looks forward to working with FDA throughout the implementation of PDUFA V.

I. GENERAL COMMENTS

To understand the Program's effect on the review of NME NDA and original BLA applications, it will be critical that the independent contractor conduct complete and accurate interim and final assessments of the Program. Accordingly, PhRMA submits the following comments:

1. Comprehensive Independent Interviews of Applicants are Key Elements of the Independent Interim and Final Assessments of the Program

FDA and industry agreed to establish the Program under PDUFA V with the goal "to improve the efficiency and effectiveness of the first cycle review process and decrease the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics."[1] The Program provides for increased communication between FDA and drug sponsors prior to and during the drug review process. PhRMA supports the FDA proposal to have Eastern Research Group, Inc. ("ERG") conduct independent interviews of applicants after the Agency issues a first-cycle action for applications reviewed under the Program. PhRMA believes that feedback collected from sponsors would improve understanding of applicant experiences with the Program and its ability to increase review transparency and communication during the review process.

2. FDA and ERG should Ensure that Appropriate Metrics are Captured during the Interviews

FDA and ERG should ensure that the proposed interviews collect appropriate metrics for the evaluation of the Program consistent with the Commitment Letter and the statement of work ("SOW")[2] for the assessment of the Program. ERG should conduct comprehensive interviews to examine the contribution of Program-related as well as non-Program actions by FDA and applicants that affect first-cycle review performance. PhRMA supports the proposal to have ERG conduct a pretest of the interview protocol with five respondents to help identify best practices.

3. FDA and ERG should Ensure that Confidentiality and Trade Secrets are Protected

FDA and ERG should ensure that any information obtained during the interviews is protected in accordance with the applicable confidentiality agreements. Applicant responses should be anonymized and aggregated prior to inclusion in the independent assessments and any presentation materials at public meeting to ensure the protection of applicants' confidential commercial information and trade secrets.

II. CONCLUSION

In summary, PhRMA supports the conduct of comprehensive independent interviews of applicants as part of the independent interim and final assessments of the Program. PhRMA emphasizes the importance of protecting confidentiality of any identifiable information obtained during applicant interviews.

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1 PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 (the "Commitment Letter"), Section II.B.

2 Assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act V; Request for Comments; 77 Fed. Reg. 40072 (July 6, 2012).

PhRMA appreciates FDA's issuance of the Notice and the opportunity to comment. We look forward to a continued dialogue and collaboration with FDA on the successful implementation of the Program under PDUFA V.

If you have any questions, please do not hesitate to contact us.

Respectfully submitted,

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PhRMA