

FY 2017 Regulatory Science Priorities



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About GPhA

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than three billion prescriptions every year. Generics represent greater than 86% of all prescriptions dispensed in the U.S





GPhA Members

3M Drug Delivery Systems

Alvogen Inc.

Amneal Pharmaceuticals LLC

ANI Pharmaceuticals

Apotex Corporation

Aurobindo Pharma USA Inc.

BD Rx, Inc.

Dr. Reddy's Laboratories, Inc.

Fresenius Kabi USA LLC

G & W Laboratories, Inc.

Glenmark Generics Inc., USA

Heritage Pharmaceuticals Inc.

Impax Laboratories, Inc.

Kremers-Urban Pharmaceuticals Inc.

Lupin Pharmaceuticals Inc.

Mallinckrodt Pharmaceuticals

Momenta Pharmaceuticals Inc.

Mylan N.V.

Natco Pharma Limited

Novel Laboratories-Gavis Pharma

Par Pharmaceutical Companies, Inc.

Perrigo PLC

Sagent Pharmaceuticals, Inc.

Sandoz Inc.

Strides Pharma Inc.

Sun Pharmaceutical Industries, Inc.

Teva Pharmaceuticals USA

Therapeutic Proteins International, LLC

West-Ward Pharmaceuticals

Wockhardt USA Inc.

Zydus Pharmaceuticals USA

GDUFA Regulatory Science – Statement of Mission

*“Make safe and effective generic drugs available to the American public by ensuring that OGD standards (as reflected in reviews, guidances and communications to sponsors and the public) continue to be based on the best currently available science and the results of regulatory science research”**

*Regulatory science and generic prescription drugs: A conversation with Rob Lionberger, Ph.D. dated June 5, 2015: <http://www.fda.gov/Drugs/NewsEvents/ucm410083.htm>

GDUFA Goals Letter States...

*“FDA will convene a **working group** and **consider suggestions from industry and other stakeholders** to develop an annual list of regulatory science initiatives for review by CDER Director.”*

- GPhA and others stakeholders began dialogue with FDA to explore how best to broaden industry's input into the development process of the annual list but to date, no plan of action has been set.
- While GPhA is supportive of the Regulatory Science Initiative, payers into the GDUFA program want more input, one annual public hearing is not enough.
- Regular reporting and communications from FDA is needed.

GPhA requests:

- Increased collaboration to identify the annual regulatory science priorities that are relevant to the generic industry;
- Increase transparency and involvement with the decision making process of the types of studies/projects funded by user fees;
- User fee funding of studies/projects to be distributed in terms of short, intermediate and long term so the generic industry can benefit from the knowledge gained from the results of these studies/projects in as real time as possible;
- FDA to establish a working group comprised of industry stakeholders per the GDUFA I Goals Commitment.

GPhA requests:

- FDA to improve transparency and communication regarding how it:
 - Determines the focus of studies/projects that are funded by the user fee program;
 - Determines the scope of the studies/projects and their benefit to the generic industry;
 - Determines how the results of the studies/projects are interpreted and utilized by the FDA, i.e. guidance development, revision to existing guidance, etc.;
 - Determines the overall impact the Science and Regulatory Initiative Program has had on increasing patient access to quality generic medicines by an independent reputable outside contractor.

Specific Areas FDA is Requesting Input On

1. Opportunities for scientific or technical advancements that would help to overcome specific barriers for industry that currently limit the availability of generic drug products.

- Discussion and expectations on nanotechnology and characterization
- Opportunities to have scientific exchange between the Industry and FDA, in the form of workshops and alike forums, to discuss the role of Emerging Technologies and its impact on the generic industry and generic product access

2. Innovative approaches to pre-approval development of generic drugs, including new methodologies for design and conduct of in vitro, ex vivo, and clinical studies and identification of scientifically robust strategies for demonstration of bioequivalence for various product classes.

- Discussion and expectations on in-vitro/in-vivo correlation (IVIVC) methods for low dose concentration products, otics, ophthalmics, long acting injectables (polymer, liposomes), autoinjectors, etc.
- Discussion and expectations on products subject to clinical endpoint studies in which the primary endpoint is difficult to measure and/or difficult to distinguish from placebo effect.
- Discussion around developing precise, well-defined in-vitro methodologies to replace the need for clinical endpoint studies for nontraditionally absorbed drug products
- Discussion and expectations on setting clinically-relevant specifications
- Discussion and expectations on qualification of dissolution apparatus and methods

3. Innovations in scientific approaches to evaluating the therapeutic equivalence of generic drug products throughout their lifecycle.

- Narrow therapeutic index products
- Drug/device combination products

4. Identification of high-impact public health issues involving generic drugs that can be addressed by the prioritized allocation of FY 2017 funding for regulatory science research.

- Timely guidance development for high impact generic products, i.e. first generics, NCE -1 products, complex

5. Identification of specific issues related to generic drug products where scientific recommendations and/or clarifications are needed in developing and/or revising FDA's guidance for industry.

- Discussion and expectations Long acting microparticles
- Discussion and expectations on aseptic processing
- Discussion and expectations on characterization of peptides and iron products
- Discussion and expectations on the characterization needed to show similarity of devices for combination products
- Discussion and expectations of risk analysis for delamination for glass vials and potential testing/specifications for delamination
- Discussion and expectations of Extractables/Leachables for all dosage forms (sterile and non-sterile)
- Discussion and expectations on generic ADF products
- Discussion on the implementation of USP General Chapter <232> Elemental Impurities
- Discussion and expectations for adhesion of transdermal products
- Updating relevant bioequivalence guidances to address the limitations with current scoring scales and statistical methodology for assessing non-inferiority of adhesion and irritation for transdermal drug products
- Discussion on risk based approach to safety evaluations of certain types of commonly used excipients

6. Strategies for enhancing quality and equivalence risk management during generic drug product development, during regulatory review, and/or throughout the drug product's lifecycle.

- Assessment of the comparative safety risk of food additives in oral drug products

Additional Points to Consider

GPhA has in past Regulatory Science Initiative public hearings provided several other key areas of concerns for the Regulatory Science Initiative Program. One such key area was for the creation of new tools by the FDA, for use in assessing the safety, effectiveness, quality, and performance of generic products. The scope of this request was to include, but not limited to, FDA addressing the concerns with regards to reviewer consistency and updating, improving, and enhancing the IID. The industry's ask on the IID was to ensure data reliability, ability of industry and FDA to make consistent and sound regulatory decisions, improve quality standards for drug development, and encourage and promote innovation. Although FDA has expressed their views that these key areas were out of scope for the Regulatory Science Initiative Program, industry is hopeful the FDA will continue its efforts to improve and enhance these areas of continued concern.

In Conclusion

GPhA looks forward to working closely with FDA and other industry stakeholders in order to develop a comprehensive and meaningful 2017 Regulatory Science Initiatives program that will benefit both the Industry and FDA.

Thank You!