U.S. Pharmacopeia
The Standard of Quality℠

August 2, 2011

Division of Dockets Management, Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, rm. 2201
Silver Spring, MD 20993-0002

Comment re: draft report, "*CDER Science Prioritization and Review Committee Identifying CDER Science and Research Needs*," Docket No. FDA-2011-D-0239

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to comment on the above-titled draft report. We support the Food and Drug Administration's (FDA) recognition of the need to build partnerships to meet the demands of globalization and leverage scarce resources.

USP collaborates with FDA in many different ways. Chief among these include development of drug quality standards enforceable by the FDA (elaborated in the *United States Pharmacopeia* and the *National Formulary* as official compendia under the Federal Food, Drug, and Cosmetic Act); quarterly meetings with FDA; and the participation of FDA liaisons in USP's standards-setting work. Other means include agreements (CRADAs) and overseas partnerships.

One of the distinct challenges USP faces in supporting state-of-the-art drug quality standards (see attachment 1, figures 1 and 2) is heavy reliance on voluntary submission of both methods and bulk materials to develop monographs and physical reference standards. This situation is made even more urgent by recent incidents of economically-motivated adulteration and the corresponding need to look for substances that are not expected to be there. Adulteration challenges compendial standards, but modern, up-to-date monographs with specific identity tests can help, as we saw recently in working with FDA and industry to revise heparin standards and help prevent a similar incident. See: http://www.usp.org/aboutUSP/impactVision/valueOfStandards/heparin.html.

We appreciate the FDA's commitment to monograph modernization and the development of reference standards, as exemplified by our collaboration with Dr. Woodcock's staff and in CRADAs USP has with FDA. Most recently, FDA staff's willingness to identify priority monograph standards for revision has significantly helped to guide USP's work, and we look forward to even greater sharing of information and guidance from, FDA. This relationship could be enhanced in multiple ways, including closer coordination between USP, FDA and industry under current legislative authority. We look forward to continued discussions with FDA.

As we also noted in recently submitted comments, facility participation in voluntary third party verification/certification programs (see www.usp.org/USPVerified) could be a consideration in developing a risk-based priority for facility inspections—something that could help improve the global supply chain. We recommend strongly that FDA seriously consider this approach as a way to accomplish its mission while conserving scarce resources. We look forward to continued collaborations and staying in close communication.

Sincerely,

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Attachment 1: Monograph Status

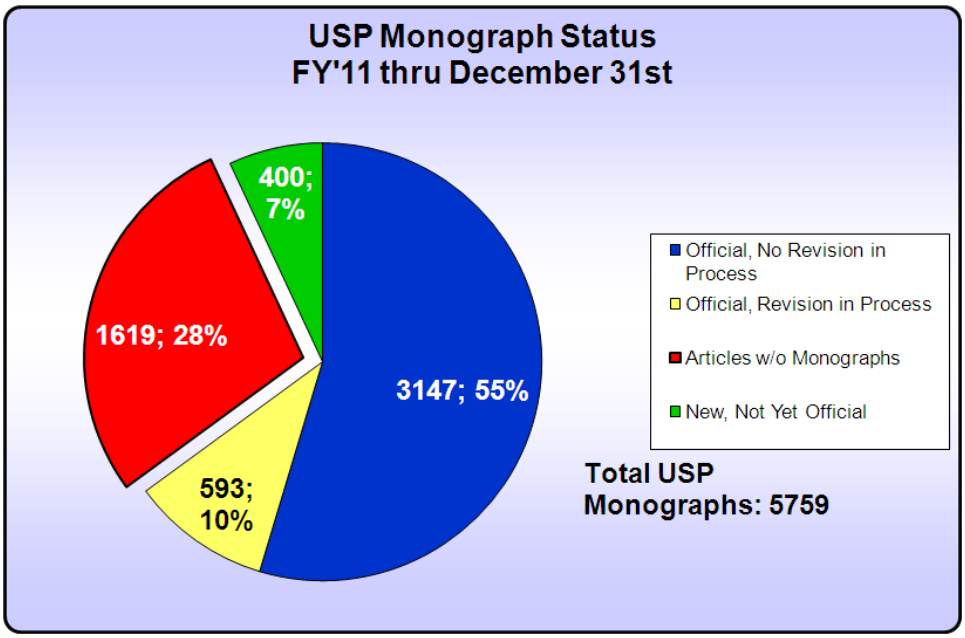

Figure 1

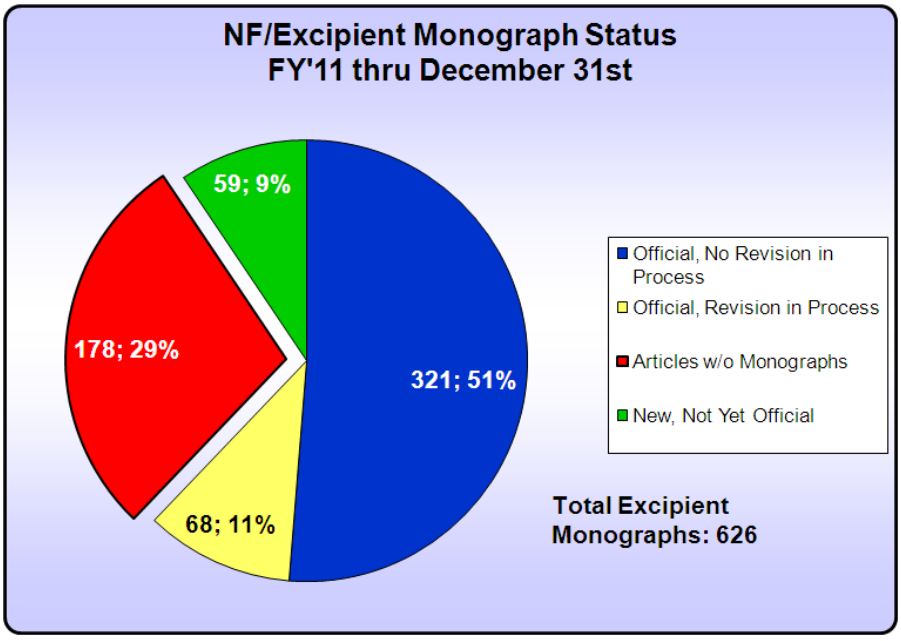

Figure 2