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March 11, 2013

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

[Submitted electronically via: www.regulations.gov/]

RE: Docket No. FDA-2013-N-0124
Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Request for Comments

Dear Sir or Madam:

Thank you for the opportunity to provide comments to the Food and Drug Administration (FDA) pursuant to the Request for Comments published in the *Federal Register* on February 12, 2013.

The National Association of Boards of Pharmacy (NABP), founded in 1904, is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

In concert with NABP's mission of protecting the public health, NABP supports FDA's efforts to address drug shortages and would like to offer the following comments.

First and foremost, FDA should clarify the current meaning of manufacturer registration and require that such registration be based upon the submission of, and approval by the FDA of, an NDA or ANDA and that all products prepared by a registered manufacturer adhere to GMP's or other requirements developed by the FDA.

NABP believes that when FDA approved sterile drugs are in shortage an exercise of enforcement discretion by FDA that subsequently allows for non-FDA approved, prepared sterile drugs to be used in place of FDA approved sterile drugs should be carefully considered, as the solution may be more dangerous to patients than the shortage itself.

In this situation, a benefit-risk assessment should be conducted that considers the following questions:

1. How essential is the drug in shortage? Is an alternative approved drug available that can be used in place of the shortage drug?

2. Can the drug product be safely prepared outside of current Good Manufacturing Practices (cGMPs)?
3. Will it cause manufacturers (NDA and ANDA holders) that manufacture the drugs in shortage to discontinue production because compounding pharmacies or approved manufacturing entities will be preparing and distributing the drug shortage products at a lower cost? In other words, will NDA and ANDA holding manufacturers be discouraged from producing drugs in shortage if compounding pharmacies or approved manufacturing entities are filling the demand for such products?

If there is no safe alternative to compounding pharmacies or approved manufacturers preparing drugs in shortage, close coordination between FDA and state pharmacy and medical boards should occur. Product preparation requirements and enforcement procedures should be put into place in order to avoid a regulatory vacuum that would allow for the preparation of such drug products absent FDA and state board of pharmacy oversight. Comprehensive communication strategies should also be initiated to inform prescribers, pharmacies, payers, and patients about the differences in products and risks associated with using these types of non-approved products. Both the entrance to and exit from the market (exit occurring when an approved manufactured product becomes available) for these prepared products should be implemented in a planned and coordinated manner. This is particularly important in the current environment for prepared drugs that enter the market under both actual and hypothetical drug shortage or access situations but then remain the primary sourced drug due to pricing even after the shortage is alleviated.

In summary, to best protect the public FDA should carefully consider using the exercise of enforcement discretion during shortages. NABP strongly encourages that a benefit-risk assessment be conducted, and if it is determined that the use of unapproved drugs is the only alternative, product preparation requirements and enforcement procedures should be put into place, a communication strategy should be initiated, and a market entrance and exit strategy for such unapproved drugs be implemented.

Thank you for the opportunity to provide comments on this issue. We look forward to continuing to work with the FDA on this important issue. If you have any questions or require additional information, please contact Melissa Madigan, NABP policy and communications director, at 847/391-4400 or mmadigan@nabp.net.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

cc: NABP Executive Committee