

June 10, 2005

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. 2005D-0021
Draft Consensus Guideline: Pharmaceutical Development Q8

Comments by the Generic Pharmaceutical Association

Dear Sir or Madam:

The Generic Pharmaceutical Association (GPhA) appreciates the opportunity to comment on the above referenced Draft Consensus Guideline. GPhA represents 98% of generic drug manufacturers whose drugs are dispensed for over half of all prescriptions filled in the United States, but representing less than 10% of all drug expenditures. GPhA is the united voice of the generic drug industry and is committed to pharmaceutical quality. GPhA would like to thank the Agency for this opportunity to provide input on the issue of Pharmaceutical Development (Q8).

The Draft Consensus Guideline for Pharmaceutical Development Q8 outlines a strategy and general approach to provide a more comprehensive understanding of the product and manufacturing process for regulators. This draft guideline addresses numerous issues and concerns related to a development of new or novel drug products. However, many aspects of this guideline do not necessarily apply to development of generic drug products as explained below.

Generic drug products must be formulated to be bioequivalent to the innovator product and in many cases exhibit other similar characteristics of the innovator product. As such, generic drug products are often formulated to be essentially the same as the innovator. Therefore, selection of the optimal formulation is often based on the innovator product which dictates the excipients and processing options. Generic drug products for parenteral, ophthalmic and otic dosage forms, by regulation, must be quantitative and qualitative the same formulation as the innovator with minor exceptions. Thus, development of these products is essentially mandated by regulation. Additionally,

topical/nasal drug products typically use a formulation that is essentially the same as the innovator product to assure bioequivalence. Thus, comprehensive product development reports would be of little value to the FDA reviewer.

The Draft Guideline also mentions justification of special design features such as tablet scoring. This is another example of when the generic drug must utilize the same special design feature (scoring) as the innovator product, hence there is little information gleaned for extensive background on such features.

The majority of formulations for generic drug products are dictated by the necessity to demonstrate in vivo bioequivalence to the innovator product, or are required to be quantitatively and qualitatively the same as the innovator. In these cases, product development reports will provide little, if any, critical information that will facilitate a better understanding by Food and Drug Administration (FDA) of product development. If product development reports are required when formulations are the same, or essentially the same, as the innovator product development reports should be very abbreviated. For those generic products that utilize a substantially different formulation or complex manufacturing process, the value of product development reports may be justified.

It should also be recognized that product development reports are already being prepared by generic manufacturers and are currently being reviewed by field inspectors at the manufacturing site. The major change being suggested is that product development reports will be included in the ANDA, requiring extensive evaluation by OGD review staff. It is not clear how this information will assist FDA in the review and approval of most drug products submitted as ANDAs.

Given the dramatic increase in the workload of the Office of Generic Drugs, and with OGD resources already stretched to the limit, GPhA requests that the Food and Drug Administration review ANDA product development requirements carefully. The information requested in the Draft Guideline will add significantly to the amount of information that OGD reviewers must evaluate. GPhA recommends that full product development reports be limited to those products for which this type of information will provide the intended insight for the FDA review staff. GPhA further encourages FDA to issue a guidance to industry that outlines the expectations for product development reports for ANDAs taking into consideration the above concerns.

Thank you for your consideration of these comments.

Sincerely,

Gordon Johnston
Vice President Regulatory Affairs