



September 19, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02D-0350
Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples

Dear Sir or Madam:

Reference is made to the August 21, 2002 Federal Register Notice, Vol. 67, No. 162, Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples. While Allergan agrees with the policy of retaining the reserve samples for Bioavailability (BA) and Bioequivalence (BE) studies at the clinical testing site, we disagree with the way in which the samples are labeled and handled at the study site.

The guidance states that for studies involving Multiple Containers, Unit Dose, and Blinded Studies that sufficient quantity of clinical supplies should be provided so the site can randomly select the test article and the reference standard with the remaining doses retained as reserve samples. This is inconsistent with the manner in which clinical supplies for randomized studies are labeled.

In preparing clinical supplies for a randomized BA or BE study, the sponsor will label test article in a masked, randomized fashion according to the randomization code supplied by the Statistician. Thus one set of samples will be supplied to the site for each patient number. When the site assigns a patient number to the subject, the investigator would then select the sample labeled with that patient number and administer the test article.

The guidance appears to require that multiple sets of samples are delivered to the study site. The site would assign a patient number to the subject and then randomly select the test article from the several test articles labeled with that patient number. We believe that this will lead to confusion, the possibility of using the same patient number for multiple subjects and therefore an unbalanced and statistically flawed study, or the possibility that the site will administer all of the test article labeled with that patient number to the subject resulting in a toxic dose.

02D-0350

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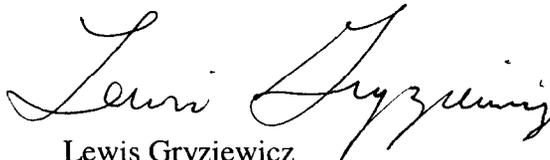
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Our proposal is to provide one set of labeled clinical supplies for each patient number along with sufficient quantity of samples to be retained by the site. By requiring that the test article and retained samples are from the same manufacturing and packaging lot and are packaged in the same manner the guidance would accomplish its intended outcome while not jeopardizing the integrity of the study or the safety of the subject.

Should you have additional questions, please contact me at (714) 246 6088.

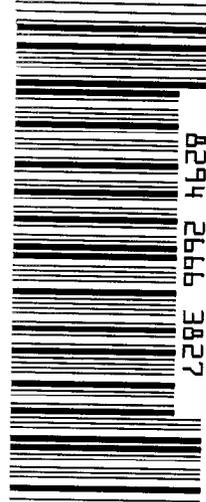
Sincerely,

A handwritten signature in cursive script, appearing to read "Lewis Gryziewicz".

Lewis Gryziewicz
Director
Regulatory Affairs

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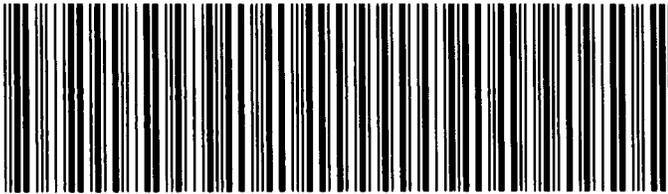
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