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December 11, 2003

VIA FEDERAL EXPRESS

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

Re: Comments on Draft Guidance – Marketed Unapproved Drugs – Compliance
Policy Guide – October 15, 2003

Dear Sir or Madam:

Our firm has reviewed the above-referenced document and submits the following
comments for consideration by the Agency.

Lines 338-340 express an opinion which, to us, appears unnecessarily hostile to
the concept of grandfathered drug products. Moreover, we are unaware of any recent
survey by the Agency intended to gather information as to the number of products in
existence which are eligible to claim this status. For these reasons, we would ask the
Agency to either delete lines 338-340 or to substitute language such as:

*The Agency recognizes that it is possible that products meeting the description of
grandfathered drug products do exist and are currently being marketed in the
United States.*

2003D-0478

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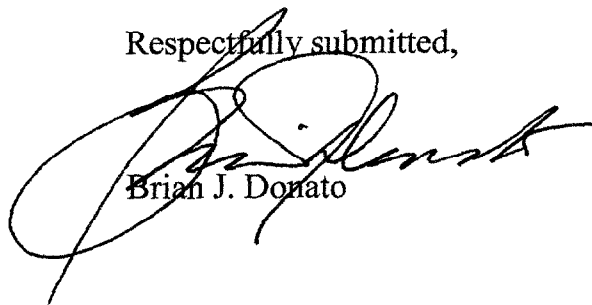
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We would appreciate your consideration of these comments and look forward to hearing your response to them.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brian J. Donato", is written over the typed name. The signature is fluid and cursive, with a large initial "B" and "D".

Brian J. Donato

bjd/mad