



**Research
and Development**

1584 '00 JAN -4 P153

Dockets Management Branch
(HFA-305)
FDA
5630 Fishers Lane
Rm. 1061
Rockville
MD 20857
USA

23 December 1999

Dear Sir/Madam

Re: Proposed Rule "New Drug and Biological Products; Evidence Needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Humans Ethically Cannot Be Conducted"

It was with considerable interest that we read about the above proposed rule in the latest edition of *PDA LETTER* – November 1999. We support the Agency's proposal to amend the new drug and biological product regulations requiring substantial evidence of efficacy of new drug and biological products used to reduce or prevent the toxicity of biological substances. We are also supportive of the Agency's recognition of the need to have adequate medical treatments to treat individuals exposed to lethal or permanently disabling toxic substances of biological nature.

We note that under this proposed rule, certain new drug and biological products intended to reduce or prevent serious or life-threatening conditions could be approved for marketing based on efficacy studies conducted in animals alone. We would like to request that antivenom and antitoxin products of animal origin be considered for inclusion specifically on the list of new drug and biological products for which this proposed rules applies.

Yours sincerely

L. Beezum

**Lorraine Beezum
REGULATORY AFFAIRS ASSOCIATE**

98N-0237

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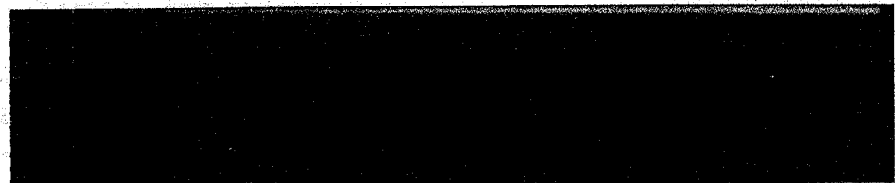
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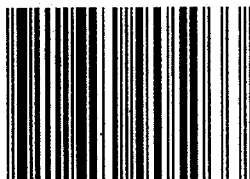
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