

CHRIS JOHN
7TH DISTRICT, LOUISIANA

COMMITTEE ON
ENERGY AND COMMERCE

SUBCOMMITTEES:
ENERGY AND AIR QUALITY
HEALTH



Congress of the United States
House of Representatives
Washington, DC 20515-1807

October 8, 2003

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Ms. Diane Prince
Legislative Analyst
Food and Drug Administration
Office of Legislation
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Prince:

I would like to take this opportunity to forward to you a letter from Ms. Janet Baron, a constituent from my district. Ms. Baron has expressed some concerns to me regarding a recently issued FDA Compliance Policy Guide on compounding practices for veterinary medicines. I would like to share these concerns with you and have you comment on them.

Please let me know if you need any assistance with this request, and I appreciate your immediate attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris John".

CHRIS JOHN
MEMBER OF CONGRESS

CJ:vel

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OCT 10 2003
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03-5006

LeBrun, Vera

From: writerep
Sent: Monday, October 06, 2003 12:02 PM
To: LA07WYR
Subject: WriteRep Responses

DATE: October 6, 2003 11:28 AM
NAME: Janet Baron
ADDR1: 150 Acacia Dr.
ADDR2: Lafayette
ADDR3:
CITY: Louisiana
STATE: Louisiana
ZIP: 70508
PHONE:
EMAIL:
msg:
Subject: Veterinary Pharmaceutical Compounding

The Center for veterinary medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets). CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options, to comment on its provisions before it is implemented.