Marne L. Platt, VMD
Novartis Animal Health US, Inc.
Regulatory Affairs Manager
3200 Northline Avenue
Suite 300
Greensboro, NC 27408
Tel (336) 387-1121
Fax (336) 387-1168
marne.platt@ah.novartis.com

NOVARTIS

6060 '01 MAY 30 A10:05

May 30, 2001

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fisher's Lane Rm. 1061
Rockville, MD 20852

Docket Number: 01D-0146, Draft Guidance Number 119, "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation if a New Animal Drug."

To Whom It May Concern:

Novartis Animal Health has reviewed the above-referenced docket, Draft Guidance Number 119, "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation if a New Animal Drug." We have the following comments and suggestions:

1. The Draft Guidance refers to minor and significant deficiencies in a submission, but fails to define those terms. We request that the Center define those terms in the revisions to this draft. For example., numerous minor protocol deviations which do not impact study outcome would be not be considered cause for rejecting a submission, while failure to provide pivotal data for more than ___% of cases enrolled would be cause to reject the submission.
2. The Draft guidance refers to the finding of flaws in the development plan as a reason for a reviewer to reject a submission. We request wording in the Guidance confirming that adherence to a Development Plan which has previously negotiated (and perhaps amended) with the Center as under proposed rule 21 CFR 514.3 will prevent the rejection of a submission for a "flawed" development plan. This will provide industry with assurance that the Center will adhere to previous agreements made with the Sponsor.
3. Please define the time impact of an amendment to a submission requested by the Center in response to minor deficiencies in a submission. The amendment should not restart the 180-day review clock for the submission. When the Sponsor submits the additional information the submission's review should be continued. The Center is already so far behind in its reviews that further resetting of the review clock will cause undue burdens upon industry.
4. Please clarify whether, in the case of resubmission of rejected submissions, the entire data package would have to be resubmitted, or only that information which would be new to the Center. Re-sending large volumes of information which the Center ahs already received wastes unnecessary time and paper in the submission and review process.

Thank you for the opportunity to comment on this proposed rule. If there are any questions, please feel free to contact me at 1-800-447-2391 ext. 1121.

Sincerely,

Marne L. Platt, VMD
Regulatory Affairs Manager

01D-0146

C1

nd your address label
ument
ill

UPS Next Day Air®
UPS Worldwide Express℠
Shipping Document

WEIGHT	WEIGHT	DIMENSIONAL WEIGHT	
	L T R		

The shipper authorizes UPS to act as forwarding agent for export control and customs purposes. The shipper certifies that these commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Diversion contrary to U.S. law is prohibited.

☐ EXPRESS (INT'L) 1

☒ DOCUMENTS ONLY 1

SATURDAY DELIVERY ☐

SHIPMENT FROM

UPS ACCOUNT NO. W467X3

REFERENCE NUMBER 5050

1Z W46 7X3 22 1002 673 3

EXPORT

1Z W46 7X3 22 1002 673 3

TELEPHONE

DR. MARNE PLATT 336-387-1035

NOVARTIS ANIMAL HEALTH US INC

3200 NORTHLINE AVE FLR 3RD RM 300

GREENSBORO NC 27408-7611

UPS Next Day Air® 1
EXTREMELY URGENT

DELIVERY TO TELEPHONE

DOCKETS MANAGEMENT BRANCH
HFA-305
FOOD AND DRUG ADMINISTRATION
5630 FISHER'S LANE, ROOM 1061

Residential ☐

ROCKVILLE, MD 20852

1Z W46 7X3 22 1002 673 3

TRACKING NUMBER

DATE OF SHIPMENT 5 /29 / 01

SHIPMENT ID NUMBER W467 X37B 4C6

0101911202609 6/00 S United Parcel Service, Louisville, KY

the rules relating to liability and other terms and/or conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (the "Warsaw Convention") *and/or the Convention on the Contract for the International*
the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited. For stopping places, call 1-800-782-7892.

1 2