

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1571]

*DMB*

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**Enrofloxacin for Poultry; Opportunity for Hearing; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

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**SUMMARY:** The Food and Drug Administration's (FDA's) Center for Veterinary Medicine (CVM), is revising a notice of opportunity for hearing (NOOH) that published in the **Federal Register** on October 31, 2000 (65 FR 64954). After publishing the NOOH, CVM determined that some estimates of numbers of human campylobacteriosis cases and fluoroquinolone-resistant *Campylobacter* cases provided by a risk assessment used as a reference in the NOOH were incorrect. CVM has revised the risk assessment and is revising the estimates that were provided in the NOOH. This notice also extends the deadline for the sponsor to submit data and analysis upon which a request for a hearing relies. Other interested persons may submit comments on the NOOH before the deadline.

**DATES:** Submit all written data and analysis upon which a request for a hearing relies and other written comments by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Data and analysis and other comments are to be identified with Docket No. 00N-1571 and must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The revised risk assessment entitled "The Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, Revised: January 5, 2001" (hereafter referred to as Ref. 2a) is available electronically at <http://www.fda.gov/cvm/antimicrobial/antimicrobial.html> and in this docket.

**FOR FURTHER INFORMATION CONTACT:** Linda Tollefson, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-2950.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 31, 2000 (65 FR 64954), CVM published an NOOH proposing withdrawal of the approval of a new animal drug application (NADA) for the use of the fluoroquinolone enrofloxacin in poultry. The NOOH included estimates that were taken from Ref. 2 of the October 31, 2000, NOOH, the risk assessment entitled "Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, October 18, 2000." After publication of the NOOH, CVM determined that two of the cell references in the risk assessment were mislabeled and as a result, the model outputs were incorrect. CVM has revised the risk assessment to correct the cell references. Because CVM needed to make these corrections to the risk assessment, it has also incorporated the final FoodNet data for 1999 into the risk assessment and has made other related changes. CVM is revising the NOOH to reflect the changes in the risk assessment and to add the revised risk assessment Ref. 2a to the list of references in the NOOH. CVM does not believe that these revisions in any way alter the underlying basis of the NOOH.

The following section describes the location and revisions to the October 31, 2000, NOOH.

**II. Revisions**

Based on the revisions to the risk assessment, CVM is revising the estimates in the October 31, 2000, NOOH for the mean estimate of cases of campylobacteriosis; the mean estimate of the domestically-acquired fluoroquinolone-resistant *Campylobacter* cases in humans attributable to consumption of chicken; and the mean estimate of the number of people who were infected with fluoroquinolone-resistant *Campylobacter* from consuming or handling chicken and who

subsequently received a fluoroquinolone as therapy for their illness. CVM is also adding the revised risk assessment to the References section of the NOOH.

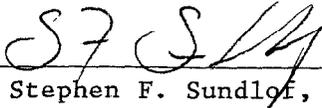
Table 1 provides the location and actual revisions of items in the NOOH.

TABLE 1.—REVISIONS TO THE OCTOBER 31, 2000, NOOH

Location	Sentence as published	Correction
64955, 2d column, beginning on the 9th line from bottom of page	The risk assessment determined *** a mean estimate of 11,477 persons (5th and 95th percentiles: 6,412 and 18,978) ***	"The risk assessment determined *** a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) ***"
64962, 1st column, beginning on the 8th line	"Using the data on human <i>Campylobacter</i> *** calculated a mean estimate of 1.7 million cases of campylobacteriosis (5th and 95th percentiles: 1.1 million and 2.7 million) for 1999 (Ref. 2)."	"Using the data on human <i>Campylobacter</i> *** calculated a mean estimate of 1.4 million cases of campylobacteriosis (5th and 95th percentiles: 0.9 million and 2.1 million) for 1999 (Ref. 2a)."
64962, 1st column, 1st full paragraph, beginning on the 7th line from the bottom of the paragraph	"For 1999, the mean estimate of *** is 190,421 (5th and 95th percentiles: 103,471 and 318,321) (Ref. 2)."	"For 1999, the mean estimate of *** is 153,580 (5th and 95th percentiles: 83,990 and 258,047) (Ref. 2a)."
64962, 1st column, 2d full paragraph, beginning on the 7th line	"For 1999, the estimated *** 11,477 (5th and 95th percentiles: 6,412 and 18,978) (Ref. 2)."	"For 1999, the estimated *** a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) (Ref. 2a)."
64962, 2d column, 1st full paragraph, beginning on the 13th line from the bottom of the paragraph	"The risk assessment determined in 1999 a mean estimate of 11, 477 people (5th and 95th percentiles: 6,412 and 18,978) ***"	"The risk assessment determined in 1999 a mean estimate of 9,261 people (5th and 95th percentiles: 5,227 and 15,326) ***"
64963, 2d column under IX. References, between Refs. 2 and 3		Insert the following reference between Refs. 2 and 3: "2a. The Human Health Impact of Fluoroquinolone Resistant <i>Campylobacter</i> Attributed to the Consumption of Chicken, Revised: January 5, 2001."

Dated: 1/16/01  
January 16, 2001.

CV011



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**



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