

should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies.

Table 1 of this document represents the estimated burden of meeting the new reporting requests. The burden estimates for these information collection requests are based on

information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) new animal drug applications (NADAs) for

antimicrobial drugs intended for use in food-producing animals.

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden for this collection of information:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section 514.1(b)(8) and 514.8(a)(2)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Hazard Identification (initial scoping of issues--relevant bacteria, resistance determinants, food products; preliminary data gathering)	5	1	5	30	150
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	5	1	5	1,000	5,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	5	1	5	8	40
Consequence Assessment (review ranking of human drug importance table)	5	1	5	4	20
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	5	1	5	12	60
Risk Management (discussion of appropriate risk management activities)	5	1	5	30	150
Total Burden					5,420

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>FDA estimates that on an annual basis an average of five NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on a review of the number of major NADA approvals that occurred between October 1997 and October 2001. During that 4-year period, an average of five antimicrobial NADAs (including original and major supplements) was approved in food-producing animals per year. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (abbreviated new animal drug applications), and certain supplemental NADAs.

Dated: September 15, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002D-0124]

#### Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled

“Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion” dated September 2003. The guidance document provides recommendations to blood collection and transfusion facilities on reporting fatalities related to human blood and blood component collection or transfusion to FDA’s Center for Biologics Evaluation and Research (CBER). The guidance announced in this notice finalizes the draft guidance of the same title dated June 2002.

**DATES:** Submit written or electronic comments on agency guidances at any time.