

Dated: June 14, 2000.
William K. Hubbard,
*Senior Associate Commissioner for Policy,
Planning, and Legislation.*
[FR Doc. 00-15429 Filed 6-20-00; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0505]

Agency Information Collection
Activities; Submission for OMB
Review; Comment Request;
Substances Prohibited From Use in
Animal Food or Feed; Animal Protein
Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration,
HHS.
ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing
that the proposed collection of
information listed below has been
submitted to the Office of Management
and Budget (OMB) for review and
clearance under the Paperwork
Reduction Act of 1995 (the PRA).
DATES: Submit written comments on the
collection of information by July 20,
2000.
ADDRESSES: Submit written comments
on the collection of information to the
Office of Information and Regulatory
Affairs, OMB, New Executive Office
Bldg., 725 17th St. NW., rm. 10235,
Washington, DC 20503, Attn: Wendy
Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:
Denver Presley, Office of Information
Resources Management (HFA-250),
Food and Drug Administration, 5600
Fishers Lane, Rockville, MD 20857,
301-827-1472.
SUPPLEMENTARY INFORMATION: In
compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.
**Title: Substances Prohibited From Use
in Animal Food or Feed; Animal
Proteins Prohibited in Ruminant Feed—
21 CFR Part 589—(OMB Control No.
0910-0339)—Extension**

Description: This rule (§ 589.2000 (21
CFR 589.2000)) provides that protein
derived from mammalian tissue (with
some exceptions) for use in ruminant
feed is a food additive subject to section
409 of the Federal Food, Drug, and
Cosmetic Act (the act) (21 U.S.C. 348).
Proteins derived from animal tissues
contained in such feed ingredients in
distribution cannot be readily identified
(i.e., species), by recipients engaged in
the manufacture, processing and
distribution, and use of animal feeds
and feed ingredients.
Thus, under the agency's authority in
section 701(a) of the act (21 U.S.C.
371(a)), to issue regulations for the
efficient enforcement of the act, this rule
places three general requirements on
persons that manufacture, blend,
process, distribute, or use products that
contain or may contain protein derived
from mammalian tissues and feeds
made from such products. The first
requirement is for cautionary labeling of
these products with direct language

developed by FDA. This labeling
requirement is exempt from the scope of
the PRA because it is a "public
disclosure of information originally
supplied by the Federal Government for
the purpose of disclosure to the public"
(5 CFR 1329.3(c)(2)).
The second requirement is for
establishments to maintain and make
available to FDA, records that are
sufficient to track any material that
contains protein derived from
mammalian tissues (as defined in
§ 589.2000(a)(1)), throughout the
material's receipt, processing, and
distribution. Based on available
information, FDA believes that
maintenance of these records is a usual
and customary part of normal business
practices for these firms. Therefore, this
recordkeeping requirement creates no
additional paperwork burden.
The third requirement is that
individuals or firms that manufacture,
blend, process, or distribute both
mammalian and nonmammalian
materials must maintain written
procedures to prevent commingling and
cross-contamination. An estimate of the
burden resulting from this
recordkeeping requirement is provided
in table 1 of this document. The
estimate is based on the time required
to develop written procedures.
Respondents to this collection of
information are individuals or firms that
manufacture, blend, process distribute,
or use feed or feed ingredients that
contain or may contain protein that may
be derived from mammalian tissue.
FDA estimates the burden of this
collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Record	Total Hours
589.2000(e)(1)(iv)	1,030	1	1,030	14	14,420

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

The estimated number of respondents,
persons that separate mammalian and
nonmammalian materials, is derived
from inspections of firms handling
animal protein intended for use in
animal feed. The estimate of the time
required for this recordkeeping
requirement is based on agency records
and communication with industry.

Dated: June 14, 2000.
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*Senior Associate Commissioner for Policy,
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[FR Doc. 00-15430 Filed 6-19-00; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Food and Drug Administration
**Biological Response Modifiers
Advisory Committee; Notice of Meeting**
AGENCY: Food and Drug Administration,
HHS.
ACTION: Notice.

This notice announces a forthcoming
meeting of a public advisory committee
of the Food and Drug Administration