a new airworthiness directive (AD), to read as follows:

Raytheon Aircraft Company (Formerly Beech, Raytheon Corporate Jets, British Aerospace, Hawker Siddley, et al.): Docket 97–NM–68–AD. Supersedes AD 96–17–10, Amendment 39–9719.

Applicability: The following models and series of airplanes, certificated in any category, equipped with AlliedSignal outflow/safety valves, as identified in AlliedSignal Aerospace Service Bulletin 103570–21–4012, Revision 1, dated May 30, 1995:

Model of airplane	Serial Nos.
400	RJ–1 through RJ–65, inclusive.
400A	RK–1 through RK–42, inclusive.
400T (military).	TT–4 and TT–19.
MU–300 ...	S/N A001SA through A091SA.
MU–300–10.	A1001SA through A1011SA, inclusive.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. for airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent cracking and consequent failure of the outflow/safety valves, which could result in rapid decompression of the airplane, accomplish the following:

(a) Within 18 months after September 24, 1996 (the effective date of AD 96–17–10, amendment 39–9719), replace the outflow/safety value in accordance with AlliedSignal Aerospace Service Bulletin 103570–21–4012, Revision 1, dated May 30, 1995.

(b) As of September 24, 1996, no person shall install an outflow/safety valve, having a part number and serial number identified in AlliedSignal Aerospace Service Bulletin 103570–21–4012, Revision 1, dated May 30, 1995, on any airplane unless that valve is considered to be serviceable in accordance with the applicable service bulletin.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then said it to the Manager, Wichita ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 24, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–20011 Filed 7–29–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 225, 510, 514, 515, and 558

[Docket No. 97N–0276]

Animal Drug Availability Act; Medicated Feed Mill Licenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the animal drug regulations to provide for feed mill licensing in accordance with the Animal Drug Availability Act (ADAA) of 1996. The ADAA amends the Federal Food, Drug, and Cosmetic Act (the act) to require a single facility license for the manufacture of feeds containing approved new animal drugs, rather than multiple medicated feed applications (MFA's) for each feed mill, as previously required by the act. The proposed regulation implements the requirements for feed mill licensing set forth in the ADAA.

DATES: Submit written comments on the proposed rule by October 28, 1997. Submit written comments on the information collection provisions by August 29, 1997. The agency proposes that any final rule that may issue based on this proposal become effective 30 days after date of publication of the final rule.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: William D. Price, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Background

The ADAA (Pub. L. 104–250), which amended section 512(a) and (m) of the act (21 U.S.C. 360b(a) and (m)), replaces the system for the approval of specific medicated feeds with a general licensing system.

Prior to the passage of the ADAA, an approved MFA was required by the act for the manufacture of medicated feed. The act required a feed mill to submit a separate MFA for each medicated feed to be manufactured by the firm. The ADAA eliminates the requirement that a feed mill submit a separate MFA for the manufacture of each type of medicated feed and instead provides for feed mills to be licensed and allows a licensed facility to manufacture any feed containing an approved new animal drug. Additionally, section 512(m)(6) of the act, as added by the ADAA, provides the agency with the authority, to the extent consistent with the public health, to exempt facilities that manufacture certain types of medicated feed from the requirement of a medicated feed mill license. The ADAA sets forth the requirements for such licensing.

The proposed regulation will require only one facility license for the manufacture of animal feeds containing approved new animal drugs, instead of multiple approved MFA's. Furthermore, those medicated feeds exempted from the MFA requirement under § 558.4 (21 CFR 558.4) will also be exempt from the requirement of a medicated feed mill license under this proposal. Thus, the regulation, in implementing the statute, would reduce the overall costs of regulatory compliance for industry. Additionally, because of the reduction in the number of applications that FDA would process annually, the proposed regulation, in implementing the statute, would reduce costs for the Federal Government.

The ADAA contains a transitional provision that provides that any person currently engaged in the manufacture of a medicated feed under an approved MFA shall be deemed to hold a medicated feed mill license for the manufacturing site identified in the application. Such transitional license

expires April 9, 1998, 18 months after the date of enactment of the ADAA, unless the person has obtained a medicated feed mill license by that date.

II. Description of the Proposed Rule

The proposed regulation implements the requirements of section 512(m) of the act for medicated feed mill licensing. The proposed rule would add a new part 515 to provide the requirements for feed mill licensing. The proposed rule would amend part 514 (21 CFR part 514) to remove the provisions regarding MFA's.

Section 515.10 sets forth the criteria for medicated feed mill license applications. Section 515.10(b)(1) requires the applicant to provide the full business name and address of the feed manufacturing facility and the facility's FDA registration number. Section 515.10(b)(2) requires the applicant to provide the name, title, and original signature of the responsible individual or individuals for that facility. Section 515.10(b)(3) requires the applicant to certify that the feed manufacturing facility is manufacturing and labeling the animal feed bearing or containing new animal drugs in accordance with applicable regulations published under section 512(i) of the act. Section 515.10(b)(4) requires the applicant to certify that the feed manufacturing facility is in conformity with current good manufacturing practice (CGMP) requirements. All of these requirements are set forth in section 512(m)(1) of the act, as amended by the ADAA.

Section 515.10(b)(5) requires the applicant to certify that the feed manufacturing facility will comply with applicable regulations or orders issued under sections 512(m)(5)(A) or 504(a)(3)(A) (21 U.S.C. 354(a)(3)(A)) of the act for record and reporting requirements. This certification requirement is based on section 512(m)(5)(A) of the act, which sets forth the agency's authority to issue record and reporting requirements applicable to medicated feed mill licensees, and section 512(m)(4)(B)(i) of the act, which sets forth the agency's authority to revoke a license for the licensee's failure to comply with such requirements.

Section 515.10(b)(6) requires the applicant to commit to the possession of current approved Type B and/or Type C medicated feed labeling for each animal feed containing an approved new animal drug. The labeling is submitted in the new animal drug application (NADA) under § 514.1(b)(3)(v)(*b*). This commitment to possess the approved labeling is based on section 512(a)(1)(B) of the act, which requires that at the time of removal of the Type A medicated article from a manufacturing, packing, or distributing establishment, such establishment must possess an unrevoked written statement from the feed manufacturing facility that such facility possesses a medicated feed mill license and current approved medicated feed labeling for the use of the Type A medicated article in animal feed. The facility can provide such a statement to the manufacturing, packing, or distributing establishment only if that facility is currently in possession of the approved labeling, which is the labeling approved in the NADA for the new animal drug in animal feed.

Section 515.10(b)(7) requires the applicant to commit to renew registration with FDA every year, in accordance with §§ 207.20 and 207.21 (21 CFR 207.20 and 207.21). Section 207.20(a) requires owners or operators of all drug establishments, not exempt under § 207.10 (21 CFR 207.10), that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs to register with FDA; and § 207.21 requires the yearly renewal of such registration. Section 207.10(f) exempts domestic establishments that manufacture only certain types of medicated feed from the registration requirement. If a feed mill manufactures any type of medicated feed that is not exempt under § 207.10(f), then the feed mill must register the establishment with FDA under § 207.20. The types of feed that would require registration of the establishment under § 207.20 would also require a medicated feed mill license under § 558.4. Thus, under §§ 207.10(f) and 558.4, each medicated feed mill that must possess a license must also register the establishment with FDA. Medicated feed mill licensees, however, are exempt from any drug listing requirement under § 207.20(a).

Section 515.10(d) provides for the return of applications that are ''facially deficient.'' The agency would apply this provision to those applications that fail to provide sufficient information for the agency to make a determination regarding approvability, such as if the application is unsigned or undated. Thus, the provision is intended to allow the agency to respond quickly to facially deficient applications so that the applicant may have an opportunity to correct the deficiencies and resubmit the application.

Section 515.11 sets forth the criteria for supplemental medicated feed mill license applications. Section 515.11(a) requires a licensee to supplement an application for a change in ownership and/or mailing address of the facility site. The relocation of the feed manufacturing facility to a new site would require the submission of a new medicated feed mill license application, because an approved license is site specific.

Section 515.11(c) requires the agency to approve a supplemental medicated feed mill license application within 30 days after the filing of such an application if the Commissioner of Food and Drugs (the Commissioner) determines that the application provides ''adequate information'' respecting the change in ownership and/or mailing address of the facility site. The agency views supplemental applications as a means to ensure the accuracy of agency records regarding a licensed site. Thus, under this provision, the supplemental application would be approved if the application provided the agency with a complete and accurate description of the change in ownership and/or mailing address of the facility site.

Section 515.11(c) also requires the agency to return supplemental applications that fail to provide adequate information respecting a change in ownership and/or mailing address of the facility site. Because of the limited nature of the changes requiring an approved supplemental application, the agency believes it would be inefficient to deny applications that do not provide adequate information regarding such a change. Therefore, a supplemental application that does not provide a complete and accurate description of a change would be returned to the applicant to complete.

Section 515.20 sets forth the requirements for the approval of medicated feed mill license applications, and § 515.21 sets forth the requirements for the refusal to approve a medicated feed mill license application. Section 515.22 sets forth the requirements for the suspension and/or revocation of a medicated feed mill license and § 515.23 provides for the voluntary revocation of a medicated feed mill license. Section 515.24 provides for the notice of revocation of medicated feed mill licenses, § 515.25 provides for the revocation of an order refusing to approve an application or suspending or revoking a license, and § 515.26 provides for the service of notices and orders.

Section 515.30 sets forth the provisions for a notice of opportunity for a hearing concerning a refusal to approve a medicated feed mill license application or a revocation of approval of a medicated feed mill license. Section 515.31 describes the procedures for hearings, and § 515.40 provides for the

judicial review of an order entered by the Commissioner.

The proposed regulation also provides conforming amendments to the Code of Federal Regulations by removing references to MFA's and inserting appropriate references to medicated feed mill licenses. In particular, the references to ''medicated feed application'' in other sections have been eliminated and replaced, where appropriate, with the new term ''medicated feed mill license.''

The proposed rule would amend § 207.10(f) in order to clarify the exemption from the requirement of establishment registration, as set forth in § 207.20. Section 207.10(f), as amended, clarifies the types of feed manufactured exclusively by a facility that would not require the registration of that facility. This clarification would make the scope of this exemption from the requirement of establishment registration identical to the scope of the exemption from the requirement of a medicated feed mill license in § 558.4(b).

The general scheme for categories and types of medicated feeds set forth in § 558.3 (21 CFR 558.3) would remain under medicated feed mill licensing. Those medicated feeds exempted from the MFA requirement under § 558.4 also would be exempt from the requirement of a medicated feed mill license under this proposal. Thus, the manufacture of a Type B or Type C medicated feed from a Category I Type A medicated article or from a Category II Type B or Type C medicated feed would be exempt from the required license, unless otherwise specified.

Section 512(m)(6) of the act, as amended by the ADAA, provides the agency with the authority, consistent with the public health, to establish such an exemption. Category I Type A medicated articles, as defined in § 558.3(b)(1), require no withdrawal period at the lowest use level in each species for which they are approved. Because Category I Type A medicated articles do not require a withdrawal period, the agency has determined that the exemption from the licensing requirement for facilities that manufacture only Type B and Type C medicated feed from Category I Type A articles, with the exception of certain types of liquid and free choice medicated feed, would be consistent with the protection of the public health. Furthermore, because Category II, Type B and Type C medicated feeds are much more dilute than the Type A medicated articles, Type B and Type C medicated feeds manufactured from Category II Type B and Type C medicated feeds are unlikely to produce unsafe (above tolerance) residues when such feed is fed to animals. Thus, the agency has determined that the exemption from the licensing requirement for facilities that manufacture only Type B or Type C medicated feeds from Category II Type B or Type C medicated feeds would be consistent with the protection of the public health.

The references to ''medicated feed application'' in the sections for liquid medicated feed (21 CFR 558.5), and free-choice medicated feed (21 CFR 510.455), will be amended in a future proposal that may incorporate substantive changes to these provisions. The agency is reviewing a citizen petition filed by the American Feed Industry Association (AFIA) on April 30, 1993, as amended on March 3, 1994, and December 6, 1996, concerning liquid medicated feed. Additionally, the references to ''medicated feed application'' in 21 CFR 558.311 and 558.355 for lasalocid and monensin, respectively, will be amended in the future proposal.

Finally, the reference to ''medicated feed application'' in the section for records and reports (21 CFR 510.301), has been changed in this proposal to ''medicated feed mill license.'' The agency intends to propose other changes to this section in a future proposal in response to a citizen petition filed by AFIA and the Animal Health Institute on November 13, 1995, as amended on December 6, 1996, concerning the records and reports requirements for medicated feed manufacturing facilities.

III. Proposed Effective Date

The agency proposes that any final rule that may issue based on this proposal become effective 30 days after date of publication of the final rule.

IV. Environmental Impact

FDA has carefully considered the potential environmental impacts of this proposed rule.

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Feed mill licensing is a procedure established by the ADAA as a replacement for FDA's previous MFA system. The proposed action substitutes a facility licensing program for a system of feed by feed approval to manufacture feeds containing approved new animal drugs, thereby substantially reducing the number of approval requests required from facilities manufacturing feeds containing new animal drugs. A medicated feed mill license authorizes a feed mill to manufacture any feed containing an approved new animal drug. Previously, a feed mill was required to submit a MFA for each applicable feed containing an approved new animal drug.

This paperwork streamlining in no way reduces the responsibility of each facility to manufacture medicated feeds in full compliance with CGMP's regulations. Nor does the proposed action prevent the FDA from inspecting facilities and their records or taking actions to bring facilities into compliance.

The licensing of a feed mill by FDA does not reduce or change the responsibilities of the mill management to comply with requirements of other Federal, State, or local workplace waste management and emissions laws and regulations. Consistent failure of a facility to comply with hazard communication requirements, to provide necessary worker protection, or to adequately manage wastes could be regarded by FDA as an indication that the facility has a systemic problem that calls into question the ability of the feed mill to comply with FDA CGMP's regulations.

V. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts and equity).

Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million.

The agency has reviewed this proposed rule and has determined that the rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA finds that the proposed rule will not be a significant regulatory action under the Executive

Order. Further, the agency finds that the proposed rule will not have a significant effect on a substantial number of small entities. Also, because the expenditures required by the proposed rule are under $100 million, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

As provided in this proposed rule, FDA would amend the process for obtaining approval to manufacture medicated feeds. Instead of requiring an approved MFA for each applicable medicated feed, this proposed regulation requires only a single facility license per feed mill, as appropriate. The ADAA grants a transitional license to all feed manufacturing facilities currently holding an approved MFA. This transitional license is valid for 18 months. During this time, the facilities can obtain a permanent license by submitting a license application and a copy of an approved MFA to FDA. One goal of this proposed rule is to streamline paperwork requirements for facilities and FDA. Despite this switch from MFA's to facility licenses, all other existing reporting responsibilities for each drug remain unchanged.

The only costs that will be incurred are the paperwork costs associated with applying for a facility license. FDA estimates that approximately 2,000 feed mills will be affected by this proposed rule, and that it will take approximately 15 minutes for each facility to complete its application. Taking 1,995 median weekly earnings of $684[1] for the executives, administrators, and managers who will complete the applications, and adding 40 percent for fringe benefits, yields average hourly earnings of $23.94. Thus, the combined paperwork costs for all facilities total $11,970 for the first year, and $599 for the estimated 100 mills expected to apply for licensing or license supplements in each subsequent year. This total cost translates into approximately $6 per mill.

Eliminating the MFA requirement provides industry with a large savings in paperwork burden. Over the past 5 years, the agency has received approximately 3,300 MFA's per year including both original applications and MFA supplements. In the past, FDA surveyed several feed mills and animal drug manufacturers, and determined that it took industry about 2 hours to complete an MFA. Therefore, FDA estimates this proposed rule will save industry over $158,000 per year, or approximately $79 per mill per year, on average. The mills that have routinely submitted a larger number of MFA's will realize a larger total savings than those mills that routinely submit fewer MFA's.

FDA will also experience a cost savings in response to the feed mill licensing requirement. Since 1994, the agency spent approximately $180,000 per year for a contractor to process the MFA's. In contrast, FDA estimates that it will take 40 minutes to process each feed mill license application at a cost of $25 per hour for a GS–13 Government employee. In the first year, it will cost the agency $33,500 to process the expected 2,000 applications, and a startup cost of $10,000 for a tracking and indexing computerized database. It is expected to cost only $1,700 to process the 100 applications for each year thereafter.

The Small Business Administration (SBA) defines all manufacturers of prepared feeds and feed ingredients for animals and fowls having 500 employees or fewer as a small business. FDA estimates that approximately 20 percent of the affected feed mills belong to large conglomerates that have an overall employee count of higher than 500. Therefore, the remaining 80 percent of the affected facilities would be considered small businesses by SBA's standards. However, the agency concludes that these altered paperwork burdens will constitute an insignificant percentage of gross revenue. FDA finds the proposed rule will provide a net economic savings for all facilities, as well as the Federal Government. Therefore, in accordance with the Regulatory Flexibility Act, FDA certifies that this proposed rule will not have a significant economic effect on a substantial number of small entities.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medicated Feed Mill License Application.

Description: This proposed rule implements the ADAA's medicated feed mill licensing provisions. It would require that any medicated feed manufacturing facility seeking a license submit an application to FDA. In § 515.10 of the proposed regulations, FDA is proposing that the medicated feed mill license application form include:

(1) Manufacturing site legal business name,
(2) Address,
(3) Phone number,
(4) Fax number,
(5) Type of application,
(6) FDA registration number, and
(7) Date and signature.

The information on the form will be used to issue medicated feed mill licenses. The information requested on the form is specifically mandated by the ADAA, except for the phone number and fax number. These numbers are needed so that FDA can contact the firm quickly when necessary. The additional burden of supplying this information is minimal.

Section 515.11 of the proposed regulations also specifies that supplemental applications must be submitted for a change in ownership and/or a change in mailing address. A medicated feed mill licensee would submit such information to FDA on the medicated feed mill license application form. Furthermore, § 515.23 of the proposed regulations also provides for voluntary revocation of the license. A medicated feed mill licensee would submit in writing to FDA a request for voluntary revocation of a license. Finally, § 515.30 of the proposed regulations provides procedures for refusing to approve license applications when, among other reasons, the application is incomplete, false, or misleading or the manufacturing, processing, and packaging of the animal feed do not comply with applicable provisions of the act. A medicated feed manufacturing facility would have the option to submit a request for a hearing

[1] *Employment and Earnings*, U.S. Department of Labor Bureau and Labor Statistics, vol. 43, No. 1, p. 205, January 1996.

in writing to FDA in response to the agency's proposal to refuse to approve a medicated feed mill license application.

Description of Respondents: Medicated feed manufacturing facilities.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN: FIRST YEAR

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	2,000	1	2,000	0.25	500
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN: EACH SUCCEEDING YEAR

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10	100	1	100	0.25	25
515.11	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30	0.15	1	0.15	24	3.6

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

FDA estimates 2,000 respondents for the submission of a medicated feed mill license application within the first year based on the number of current MFA holders (approximately 2,000). Furthermore, FDA estimates 100 respondents for the submission of a medicated feed mill license application during each succeeding year based on the average number of new firms that began to manufacture medicated feed in past years. FDA estimates 25 respondents per year for the submission of supplements based on the average number of supplements that FDA received for MFA's in past years. FDA estimates 50 respondents per year for the submission of voluntary revocation requests based on the average number of cancellation requests that FDA received for feed mill registration in past years. Finally, FDA estimates 0.15 respondents per year for the submission of hearing requests based on the fact that FDA received only approximately five such requests for MFA's in the past 33 years.

FDA has already begun accepting and acting on feed mill license applications in accordance with its statutory authority to do so under the ADAA. This proposed rule would not significantly change the application form that is now being used for such applications. To allow FDA to begin implementing the ADAA promptly, the OMB approved this collection of information, including the use of the application Form FDA 3448, on a temporary basis under the emergency processing provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(j)). The approval is under OMB control number 0910–0337 and it was announced in a notice published in the **Federal Register** of March 31, 1997 (62 FR 15186). The March 31, 1997, **Federal Register** notice solicited public comment on the collection of information and provided 60 days for such comments. FDA received no comments in response to this notice.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by August 29, 1997, to (address above).

VII. Request for Comments

Interested persons may, on or before, October 28, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons may, on or before August 29, 1997, submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB (address above).

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 515

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that title 21 of the Code of Federal Regulations be amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: Secs. 301, 501, 502, 505, 506, 507, 510, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 355, 356, 357, 360, 360b, 371, 374); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 207.10 is amended by revising paragraph (f) to read as follows:

§ 207.10 Exemptions for domestic establishments.

* * * * *

(f) Persons who only manufacture the following:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds, and/or;

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(3) Persons who manufacture free-choice feeds, as defined in § 510.455 of this chapter, or medicated liquid feeds, as defined in § 558.5 of this chapter, where a medicated feed mill license is required are not exempt.

* * * * *

§ 207.20 [Amended]

3. Section 207.20 *Who must register and submit a drug list* is amended in paragraph (c) by removing the words ''medicated feed application,'' and adding in its place ''medicated feed mill license application,''.

§ 207.21 [Amended]

4. Section 207.21 *Times for registration and drug listing* is amended in paragraph (a), in the second sentence, by removing the phrase ''medicated feed application,'' and adding in its place ''medicated feed mill license application,''.

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

5. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 374).

6. Section 225.1 is amended by revising paragraph (b)(2) and by adding a new paragraph (c) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(b) * * *

(2) The regulations in §§ 225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in §§ 225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which an approved license is not required.

(c) In addition to the recordkeeping requirements in this part, Type B and Type C medicated feeds made from Type A articles or Type B feeds under approved new animal drug applications and a medicated feed mill license are subject to the requirements of § 510.301 of this chapter.

§ 225.58 [Amended]

7. Section 225.58 *Laboratory controls* is amended in paragraph (b)(1) by revising the first sentence to read ''For feeds requiring a medicated feed mill license (Form FDA 3448) for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter.''

8. Section 225.115 is amended by revising paragraph (b)(2) to read as follow:

§ 225.115 Complaint files.

* * * * *

(b) * * *

(2) For medicated feeds whose manufacture require a medicated feed mill license (Form FDA 3448), records and reports of clinical and other experience with the drug shall be maintained and reported, under § 510.301 of this chapter.

PART 510—NEW ANIMAL DRUGS

9. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376e).

10. Section 510.301 is amended by revising the section heading to read as follows:

§ 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

* * * * *

11. Section 510.305 is revised in its entirety to read as follows:

§ 510.305 Maintenance of copies of approved medicated feed mill licenses to manufacture animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location on the premises of each establishment:

(a) A copy of the approved medicated feed mill license (Form FDA 3448); and

(b) Approved labeling for Type B and/or Type C feeds being manufactured.

PART 514—NEW ANIMAL DRUG APPLICATIONS

12. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 379e, 381).

§ 514.2 [Removed]

13. Section 514.2 *Applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.9 [Removed]

14. Section 514.9 *Supplemental applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.105 [Amended]

15. Section 514.105 *Approval of applications* is amended by removing paragraph (b) and by redesignating paragraphs (a)(1) and (a)(2) as paragraphs (a) and (b) and by removing the designation ''(a)'' from the first paragraph.

§ 514.111 [Amended]

16. Section 514.111 *Refusal to approve an application* is amended by removing paragraph (b) and redesignating paragraph (c) as paragraph (b).

§ 514.112 [Removed]

17. Section 514.112 *Return of applications for animal feeds bearing or containing new animal drugs* is removed.

§ 514.115 [Amended]

18. Section 514.115 *Withdrawal of approval of applications* is amended in paragraphs (a), (b), (c), and (d) by removing the phrase ''or (m)(2)''; in paragraph (c)(1) by removing the phrases ''or (m)(5)(A)'' and ''or (m)(5)(B)''; in paragraph (c)(3) by removing the phrase ''or animal feed''; and in paragraph (e) by removing the second sentence.

19. Section 514.201 is revised to read as follows:

§ 514.201 Procedures for hearings.

Hearings relating to new animal drugs under section 512(d) and (e) of the act shall be governed by part 12 of this chapter.

20. Part 515 is added to read as follows:

PART 515—MEDICATED FEED MILL LICENSE

Subpart A—Applications

Sec.
515.10 Applications for licenses to manufacture animal feeds bearing or containing new animal drugs (medicated feed mill license).
515.11 Supplemental medicated feed mill license applications.

Subpart B—Administrative Actions on Licenses

515.20 Approval of medicated feed mill license applications.
515.21 Refusal to approve a medicated feed mill license application.
515.22 Suspension and/or revocation of approval of a medicated feed mill license.
515.23 Voluntary revocation of medicated feed mill license.
515.24 Notice of revocation of a medicated feed mill license.
515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.
515.26 Service of notices and orders.

Subpart C—Hearing Procedures

515.30 Contents of notice of opportunity for a hearing.
515.31 Procedures for hearings.

Subpart D—Judicial Review

515.40 Judicial review.

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

Subpart A—Applications

§ 515.10 Applications for licenses to manufacture animal feeds bearing or containing new animal drugs (medicated feed mill license).

(a) Applications (Form FDA 3448) to be filed under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) shall be completed, signed, and submitted in the form described in paragraph (b) of this section to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(b) Each application for a license to manufacture animal feeds bearing or containing new animal drugs shall include the following information:

(1) A full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's FDA registration number assigned under section 510 of the act.

(2) The name, title, and original signature of the responsible individual or individuals for that facility.

(3) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published under section 512(i) of the act.

(4) A certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B) of the act and part 225 of this chapter.

(5) A certification that the facility will establish and maintain all records required by regulation or order issued under section 512(m)(5)(A) or 504(a)(3)(A) of the act, as published in § 515.30, and will permit access to, or copying or verification of such records.

(6) A commitment that current approved Type B and/or Type C medicated feed labeling for each animal drug in animal feed will be in the possession of the feed manufacturing facility prior to receiving the Type A medicated article containing such drug.

(7) A commitment to renew registration every year with FDA as required in §§ 207.20 and 207.21 of this chapter.

(c) Upon approval, the original copy of the application will be signed by an authorized employee of the Food and Drug Administration designated by the Commissioner of Food and Drugs, and a copy will be returned to the applicant.

(d) Applications that are facially deficient will be returned to the applicant. All reasons for the return of the application will be made known to the applicant.

(e) Applications (Form FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

§ 515.11 Supplemental medicated feed mill license applications.

(a) After approval of a medicated feed mill license application to manufacture animal feed, a supplemental application shall be submitted for a change in ownership and/or a change in mailing address of the facility site.

(b) Each supplemental application should be accompanied by a fully completed Form FDA 3448 and include an explanation of the change.

(c) Within 30 working days after a supplemental application has been filed, if the Commissioner of Food and Drugs determines that the application provides adequate information respecting the change in ownership and/or postal address of the facility site, then he shall notify the applicant that it is approvable by signing and mailing to the applicant a copy of the Form FDA 3448. Supplemental applications that do not provide adequate information shall be returned to the applicant and all reasons for the return of the application shall be made known to the applicant.

Subpart B—Administrative Actions on Licenses

§ 515.20 Approval of medicated feed mill license applications.

Within 90 days after an application has been filed under § 515.10, if the Commissioner of Food and Drugs determines that none of the grounds for denying approval specified in section 512(m)(3) of the Federal Food, Drugs, and Cosmetic Act applies, he shall notify the applicant that it is approved by signing and mailing to the applicant a copy of the Form FDA 3448.

§ 515.21 Refusal to approve a medicated feed mill license application.

(a) The Commissioner of Food and Drugs shall within 90 days, or such additional period as may be agreed upon by the Commissioner and the applicant, after the filing of an application under § 515.10, inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, on the basis of a preapproval inspection, or upon the basis of any other information before him that:

(1) The application is incomplete, false, or misleading in any particular; or

(2) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(3) The facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animals feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are

published under section 512(i) of the Federal Food, Drug, and Cosmetic Act.

(b) The Commissioner, as provided in § 515.30, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

(1) Withdraws the application; or

(2) Waives the opportunity for a hearing; or

(3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

§ 515.22 Suspension and/or revocation of a medicated feed mill license application.

(a) The Secretary may suspend a medicated feed mill license approved under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act and give the person holding the medicated feed mill license application prompt notice of his action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended.

(b) The Commissioner of Food and Drugs shall notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if he finds:

(1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing a supplemental application under § 515.11.

(c) The Commissioner may notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if he finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under section 512(m)(5)(A) or 504(a)(3)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by section 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to ensure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

§ 515.23 Voluntary revocation of medicated feed mill license.

A license issued under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under § 558.4 of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

§ 515.24 Notice of revocation of a medicated feed mill license.

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act is revoked by the Commissioner, he will give appropriate public notice of such action by publication in the Federal Register.

§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

The Commissioner of Food and Drugs, upon his own initiative or upon request of an applicant stating reasonable grounds therefor and if he finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

§ 515.26 Service of notices and orders.

All notices and orders under this part and section 512 of the Federal Food, Drug, and Cosmetic Act pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at his last known address in the records of the Food and Drug Administration.

Subpart C—Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which he proposes to issue his order. On request of the applicant, the Commissioner will explain the reasons for his action. The notice of opportunity for a hearing will be published in the **Federal Register** and will specify that the applicant has 30 days after issuance of the notice within which he is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, his failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, he is required to file a written appearance requesting the hearing

within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information he is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and he shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in his appearance.

§ 515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs. In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

21. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.3 [Amended]

22. Section 558.3 *Definitions and general considerations applicable to this part* is amended in paragraphs (b)(2) and (b)(5) by removing the phrase ''an application approved under 514.105(a) of this chapter'' and in paragraphs (b)(3)and (b)(4) by removing the phrase ''an application approved under § 514.105(b) of this chapter'' and adding in their places ''a medicated feed mill license application approved under § 515.20 of this chapter''.

23. Section 558.4 is amended by revising the section heading and paragraphs (a), (b), and (c) to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

* * * * *

Dated: July 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–19820 Filed 7–29–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 924

[SPATS No. MS–012–FOR]

Mississippi Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Mississippi regulatory program (hereinafter the ''Mississippi program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to the Mississippi Surface Coal Mining and Reclamation Law pertaining to definitions, reorganization, adoption of rules and regulations, small operator assistance program, permit applications, permit fees, reclamation plans, performance bonds, permit issuance, permit reissuance, permit revision, public participation, public hearings, formal hearings, confidentiality claims, environmental protection performance standards, postmining land use, underground coal mining, mine entrance signs, violation complaints, civil penalties, bond release, bond forfeiture, suspension and revocation of permits, designating lands unsuitable for surface coal mining, and creation of a ''Surface Coal Mining and Reclamation Fund.'' The amendment is intended to revise the Mississippi program to be consistent with SMCRA, clarify ambiguities, and improve operational efficiency.

This document sets forth the times and locations that the Mississippi program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., c.d.t., August 29, 1997. If requested, a public hearing on the proposed amendment will be held on August 25, 1997. Requests to speak at the hearing must be received by 4:00 p.m., c.d.t. on August 14, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Arthur