

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Grain Inspection, Packers and Stockyards Administration

#### 7 CFR Part 800

[Docket No. FGIS-2001-001b]

RIN: 0580-AA75

#### Fees for Official Inspection and Official Weighing Services

**AGENCY:** Grain Inspection, Packers and Stockyards Administration, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Federal Grain Inspection Service (FGIS) of the Grain Inspection, Packers and Stockyards Administration (GIPSA) is increasing fees by approximately 6.1 percent. Contract and noncontract hourly rates, certain unit rates, and the administrative tonnage fee are increased. These fees apply only to official inspection and weighing services performed in the United States under the United States Grain Standards Act (USGSA), as amended. This fee increase of approximately 6.1 percent is based on the cost-of-living increases utilizing an average of the locality pay adjustments and actual cost of performing official inspection services of 2.4 percent and 3.7 percent in fiscal year (FY) 2000 and FY 2001, respectively. GIPSA anticipates the increase in the user fees will generate approximately \$575,000 in additional revenue.

**EFFECTIVE DATE:** August 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** David Orr, Director, Field Management Division, at his E-mail address: [Dorr@gipsadc.usda.gov](mailto:Dorr@gipsadc.usda.gov), or telephone him at (202) 720-0228.

**SUPPLEMENTARY INFORMATION:**

#### Executive Order 12866, Regulatory Flexibility Act, and the Paperwork Reduction Act

This rule has been determined to be nonsignificant for the purpose of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Also, pursuant to the requirements set forth in the Regulatory Flexibility Act, it has been determined that this final rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

GIPSA regularly reviews its user-fee-financed programs to determine if the fees are adequate. GIPSA has and will continue to seek out cost saving opportunities and implement appropriate changes to reduce costs. However, even with these efforts, GIPSA's existing fee schedule will not generate sufficient revenues to cover program costs while maintaining an adequate reserve balance. In FY 1999, GIPSA's operating costs were \$23,176,643 with revenue of \$22,971,204, resulting in a negative margin of \$205,440. In FY 2000, GIPSA's operating costs were \$24,146,428 with revenue of \$23,150,188 that resulted in a negative margin of \$996,240 and a negative reserve balance of \$938,147. Using the most recent data available as of April 30, 2001, GIPSA's FY 2001 operating costs were \$14,988,809 with revenue of \$14,348,665 that resulted in a negative margin of \$640,144. The current reserve negative balance of \$954,547 continues to remain well below the desired 3-month reserve of approximately \$3 million. In addition, GIPSA has revised its tonnage workload projection from 82 million metric tons to 79 million metric tons for FY 2001. This decrease in tonnage will adversely affect revenues. Notwithstanding GIPSA's efforts to contain and reduce costs, it anticipates that operating costs will continue to outpace revenues during FY 2001 and, therefore, additional fee increases are likely in the future.

Employee salaries and benefits are major program costs that account for approximately 84 percent of FGIS's total operating budget. Effective May 1, 2000, GIPSA increased fees as published March 30, 2000, in the **Federal Register** (65 FR 16783), by 2.4 percent. The

average Federal salary increase effective January 2000 was 4.8 percent. GIPSA had anticipated that savings could offset the remaining 2.4 percent of the Federal salary increase. GIPSA had anticipated an increase in metric tons inspected and/or weighed which in conjunction with a projected decrease in the number of paid hours could have offset the remaining half of the Federal salary increase. However, there was a 7 percent decrease in metric tons FGIS inspected in FY 2000. This decrease caused a reduction in hours billed. FGIS also experienced a shift from noncontracted service hours to contracted service hours, which caused an increase in nonrevenue productive hours in some locations. These factors were not enough to offset the remaining 2.4 percent Federal salary increases. The salary increase that became effective January 2001 averages 3.7 percent for FGIS employees. This final rule will increase overall program revenues by approximately \$575,000.

The fee increase primarily applies to entities engaged in the export of grain. Under the provisions of the USGSA, grain exported from the United States must be officially inspected and weighed. Mandatory inspection and weighing services are provided by GIPSA on a fee basis at 37 export facilities. All of these facilities are owned and managed by multi-national corporations, large cooperatives, or public entities that do not meet the criteria for small entities established by the Small Business Administration.

Some entities that request nonmandatory official inspection and weighing services at other than export locations could be considered small entities. The impact on these small businesses would be to incur an approximate 6.1 percent increase in the cost of official inspection and weighing services. This increase should not significantly affect any business requesting official inspection and weighing services. Furthermore, any of these small businesses that wish to avoid the fee increase may elect to do so by using an alternative source for inspection and weighing services. Such a decision should not prevent the business from marketing its products.

There would be no additional reporting or recordkeeping requirements imposed by this action. In compliance with the Paperwork Reduction Act of

1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements in Part 800 have been previously approved by the Office of Management and Budget under control number 0580-0013. GIPSA has not identified any other Federal rules which may duplicate, overlap, or conflict with this final rule.

**Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This action is not intended to have a retroactive effect. The USGSA provides in § 87g that no subdivision may require or impose any requirements or restrictions concerning the inspection, weighing, or description of grain under the Act. Otherwise, this final rule will not preempt any State or local laws, regulations, or policies unless they present irreconcilable conflict with this final rule. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule.

**Background**

On April 4, 2001, GIPSA proposed in the **Federal Register** (66 FR 17817) to increase fees for official inspection and weighing services performed under the USGSA (7 U.S.C. 71 *et seq.*) by approximately 6.1 percent. The USGSA authorizes GIPSA to provide official grain inspection and weighing services and to charge and collect reasonable

fees for performing these services. The fees collected are to cover, as nearly as practicable, GIPSA's costs for performing these services, including related administrative and supervisory costs. The current USGSA fees were published in the **Federal Register** on March 30, 2000 (65 FR 16783), and became effective on May 1, 2000.

GIPSA regularly reviews its user-fee-financed programs to determine if the fees are adequate. GIPSA has and will continue to seek out cost saving opportunities and implement appropriate changes to reduce costs. However, even with these efforts, GIPSA's existing fee schedule will not generate sufficient revenues to cover program costs while maintaining an adequate reserve balance. In FY 1999, GIPSA's operating costs were \$23,176,643 with revenue of \$22,971,204, resulting in a negative margin of \$205,440. In FY 2000, GIPSA's operating costs were \$24,146,428 with revenue of \$23,150,188 that resulted in a negative margin of \$996,240 and a negative reserve balance of \$938,147. As of April 30, 2001, GIPSA's FY 2001 operating costs were \$14,988,809 with revenue of \$14,348,665 that resulted in a negative margin of \$640,114. The current reserve negative balance of \$954,547 continues to be well below the desired 3-month reserve of approximately \$3 million.

Employee salaries and benefits are major program costs that account for approximately 84 percent of GIPSA's

total operating budget. Effective May 1, 2000, GIPSA increased fees as published March 30, 2000, in the **Federal Register** (65 FR 16783), by 2.4 percent. The average Federal salary increase that became effective January 2000 was 4.8 percent. GIPSA had anticipated that savings could offset the remaining 2.4 percent of the Federal salary increase. GIPSA had anticipated an increase in metric tons inspected and/or weighed which in conjunction with a projected decrease in the number of paid hours could have offset the remaining half of the Federal salary increase. However, there was a 7 percent decrease in metric tons FGIS inspected in FY 2000. This decrease caused a reduction in hours billed. FGIS also experienced a shift from noncontracted service hours to contracted service hours, which caused an increase in nonrevenue productive hours in some locations. These factors were not enough to offset the remaining 2.4 percent Federal salary increases. The salary increase that became effective January 2001 averages 3.7 percent for FGIS employees.

We have reviewed the financial position of our inspection and weighing program based on the increased salary and benefit costs, along with the projected FY 2001 workload of 82 million metric tons. Based on the review, we have concluded that an approximate 6.1 percent increase will have to be recovered at this time through increases in fees.

The current hourly fees are:

	Monday to Friday (6 a.m. to 6 p.m.)	Monday to Friday (6 p.m. to 6 a.m.)	Saturday, Sunday, and Overtime	Holidays
1-year contract .....	\$25.80	\$28.00	\$36.40	\$43.60
6-month contract .....	28.40	30.20	38.60	50.60
3-month contract .....	32.40	33.40	42.00	52.20
Noncontract .....	37.60	39.60	48.00	59.00

GIPSA has also identified certain unit fees, for services not performed at an applicant's facility, that contain direct labor costs and would require a fee increase. Further, GIPSA has identified those costs associated with salaries and benefits that are covered by the administrative metric tonnage fee. The 6.1 percent cost-of-living increase to salaries and benefits covered by the administrative tonnage fee results in an overall increase of an average of 6.1 percent to the administrative tonnage fee. Accordingly, GIPSA is increasing certain hourly rates, certain unit rates, and the administrative tonnage fee in 7

CFR 800.71, Table 1-Fees for Official Services Performed at an Applicant's Facility in an Onsite FGIS Laboratory; Table 2-Services Performed at Other Than an Applicant's Facility in an FGIS Laboratory; and Table 3, Miscellaneous Services.

**Comment Review**

GIPSA received one comment during the 30-day comment period from a grain trade association. The trade association stated that it consists of 1,000 grain, feed, processing and grain-related companies, 70 percent of which are small entities. The commenter did not

support the proposed rule. A summary of the comment and GIPSA's response is as follows:

The commenter stated that the proposed fee increase was excessive and suggested GIPSA offset anticipated increases in costs for this fiscal year through improved operating efficiencies and additional reductions in overhead. In addition, the commenter suggested GIPSA aggressively seek ways to reduce direct employee expenses through increased automation and contracting for official services so future mandated Federal pay increases will have less

impact on the cost of providing official services.

GIPSA disagrees that the approximate 6.1 percent fee increase is excessive. GIPSA is constantly exploring actions to reduce official inspection and weighing costs. However, as previously discussed in this final rule, unexpected export market developments and actions during the past year have reduced projected revenue. During the past 2 years, there has been a 12.7 percent shift from non-contract to contract services. This shift from non-contract to contract services generates less revenue for GIPSA. Furthermore, the use of more efficient export facilities has resulted in more metric tons loaded per hour while using fewer GIPSA official inspection and weighing personnel to provide that service. Consequently, there has been a 10.8 percent decrease in non-contract-billed hours and a 14 percent reduction in paid hours.

The USGSA requires GIPSA to maintain a workforce of sufficient size and experience to meet the inspection and weighing needs of its applicants. GIPSA views its skilled and well-trained employees as valuable resources which facilitate the marketing of grain. Whenever possible, GIPSA has replaced vacant full time permanent positions with part time and intermittent employees to reduce administrative overhead costs related to employee salaries and benefits. Further, GIPSA is constantly reviewing the inspection and weighing programs to assess service

delivery and service demand. Whenever possible, available employees are used for temporary duty assignments within other Federal programs to further reduce administrative overhead costs. This action allows GIPSA the ability to temporarily downsize while maintaining a skilled and well-trained workforce available for duty when service demands increase. GIPSA is also reviewing the issue of contracting for official services when appropriate. Efforts to contain and reduce costs have and will continue to be a high priority issue with GIPSA. GIPSA has and will continue to take action to reduce inspection and weighing costs whenever possible.

**Final Action**

In the April 4, 2001, proposal there were four errors. The first error occurred on page 17817, column 2. The revenue figure for FY 2001 should have read \$6,326,583. The second error occurred in Table 1(1) Inspection and Weighing Services Hourly Rates (for service personnel). The hourly rates for the 3- and 6-month contract rates were transposed. The correct rates are that the 3-month contract hourly rates are higher than the 6-month contract hourly rates. The third error occurred in Table 2(3) Stowage examination. The minimum fee for a ship should have read \$255, not \$252.50; the minimum fee for a ship reinspection should have read \$153, not \$151.50. The fourth error was corrected in a Federal Register document

published on April 16, 2001 (66 FR 19608). The document corrected the E-mail address for comments and the Table 1 heading on page 17819.

Accordingly, GIPSA is applying an approximate 6.1 percent increase to hourly rates, certain unit rates, and the administrative tonnage fee, as proposed, in 7 CFR 800.71. Table 1—Fees for Official Services Performed at an Applicant’s Facility in an Onsite GIPSA Laboratory; Table 2—Services Performed at Other Than an Applicant’s Facility in a GIPSA Laboratory; and Table 3—Miscellaneous Services.

**List of Subjects in 7 CFR Part 800**

Administrative practice and procedure; Grain.

For the reasons set out in the preamble, 7 CFR Part 800 is amended as follows:

**PART 800—GENERAL REGULATIONS**

1. The authority citation for part 800 continues to read as follows:

**Authority:** Pub. L. 94–582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*)

2. Section 800.71 is amended by revising Schedule A in paragraph (a) to read as follows:

**§ 800.71 Fees assessed by the Service.**

(a) \* \* \*

**Schedule A.—Fees for Official Inspection and Weighing Services Performed in the United States**

TABLE 1.—FEES FOR OFFICIAL SERVICES PERFORMED AT AN APPLICANT’S FACILITY IN AN ONSITE FGIS LABORATORY <sup>1</sup>

	Monday to Friday (6 a.m. to 6 p.m.)	Monday to Friday (6 p.m. to 6 a.m.)	Saturday, Sunday, and Over-time <sup>2</sup>	Holidays
1-year contract .....	\$27.40	\$29.80	\$38.60	\$46.40
6-month contract .....	30.20	32.00	41.00	53.60
(1) Inspection and Weighing Services Hourly Rates (per service representative)				
3-month contract .....	34.40	35.60	44.60	55.40
Noncontract .....	40.00	42.00	51.00	62.60
(2) Additional Tests (cost per test, assessed in addition to the hourly rate) <sup>3</sup>				
(i) Aflatoxin (other than Thin Layer Chromatography) .....				\$8.50
(ii) Aflatoxin (Thin Layer Chromatography method) .....				20.00
(iii) Corn oil, protein, and starch (one or any combination) .....				1.50
(iv) Soybean protein and oil (one or both) .....				1.50
(v) Wheat protein (per test) .....				1.50
(vi) Sunflower oil (per test) .....				1.50
(vii) Vomitoxin (qualitative) .....				12.50
(viii) Vomitoxin (quantitative) .....				18.50
(ix) Waxy corn (per test) .....				1.50
(x) Fees for other tests not listed above will be based on the lowest noncontract hourly rate.				
(xi) Other services				
(a) Class Y Weighing (per carrier)				
(1) Truck/container .....				.30
(2) Railcar .....				1.25
(3) Barge .....				2.50
(3) Administrative Fee (assessed in addition to all other applicable fees, only one administrative fee will be assessed when inspection and weighing services are performed on the same carrier).				
(i) All outbound carriers (per-metric-ton) <sup>4</sup>				

(a) 1–1,000,000 .....	\$0.1101
(b) 1,000,001–1,500,000 .....	0.1005
(c) 1,500,001–2,000,000 .....	0.0543
(d) 2,000,001–5,000,000 .....	0.0402
(e) 5,000,001–7,000,000 .....	0.022
(f) 7,000,001 + .....	0.0100

<sup>1</sup> Fees apply to original inspection and weighing, reinspection, and appeal inspection service and include, but are not limited to, sampling, grading, weighing, prior to loading stowage examinations, and certifying results performed within 25 miles of an employee's assigned duty station. Travel and related expenses will be charged for service outside 25 miles as found in § 800.72 (a).

<sup>2</sup> Overtime rates will be assessed for all hours in excess of 8 consecutive hours that result from an applicant scheduling or requesting service beyond 8 hours, or if requests for additional shifts exceed existing staffing.

<sup>3</sup> Appeal and reinspection services will be assessed the same fee as the original inspection service.

<sup>4</sup> The administrative fee is assessed on an accumulated basis beginning at the start of the Service's fiscal year (October 1 each year).

TABLE 2.—SERVICES PERFORMED AT OTHER THAN AN APPLICANT'S FACILITY IN AN FGIS LABORATORY<sup>1 2</sup>

(1) Original Inspection and Weighing (Class X) Services	
(i) Sampling only (use hourly rates from Table 1)	
(ii) Stationary lots (sampling, grade/factor, & checkloading)	
(a) Truck/trailer/container (per carrier) .....	\$19.00
(b) Railcar (per carrier) .....	28.60
(c) Barge (per carrier) .....	181.00
(d) Sacked grain (per hour per service representative plus an administrative fee per hundredweight) (CWT) .....	0.02
(iii) Lots sampled online during loading (sampling charge under (i) above, plus):	
(a) Truck/trailer container (per carrier) .....	9.85
(b) Railcar (per carrier) .....	19.10
(c) Barge (per carrier) .....	108.10
(d) Sacked grain (per hour per service representative plus an administrative fee per hundredweight) (CWT) .....	0.02
(iv) Other services	
(a) Submitted sample (per sample—grade and factor) .....	11.20
(b) Warehouseman inspection (per sample) .....	19.00
(c) Factor only (per factor—maximum 2 factors) .....	5.00
(d) Checkloading/condition examination (use hourly rates from Table 1, plus an administrative fee per hundredweight if not previously assessed) (CWT) .....	0.02
(e) Reinspection (grade and factor only. Sampling service additional, item (i) above) .....	12.40
(f) Class X Weighing (per hour per service representative) .....	52.50
(v) Additional tests (excludes sampling)	
(a) Aflatoxin (per test—other than TLC method) .....	28.00
(b) Aflatoxin (per test—TLC method) .....	106.00
(c) Corn oil, protein, and starch (one or any combination) .....	8.60
(d) Soybean protein and oil (one or both) .....	8.60
(e) Wheat protein (per test) .....	8.60
(f) Sunflower oil (per test) .....	8.60
(g) Vomitoxin (qualitative) .....	29.50
(h) Vomitoxin (quantitative) .....	36.50
(i) Waxy corn (per test) .....	9.85
(j) Canola (per test—00 dip test) .....	9.85
(k) Pesticide Residue Testing <sup>3</sup> .	
(1) Routine Compounds (per sample) .....	207.00
(2) Special Compounds (per service representative) .....	106.00
(l) Fees for other tests not listed above will be based on the lowest noncontract hourly rate from Table 1.	
(2) Appeal inspection and review of weighing service. <sup>4</sup>	
(i) Board Appeals and Appeals (grade and factor) .....	79.00
(a) Factor only (per factor—max 2 factors) .....	41.50
(b) Sampling service for Appeals additional (hourly rates from Table 1).	
(ii) Additional tests (assessed in addition to all other applicable fees)	
(a) Aflatoxin (per test, other than TLC) .....	27.50
(b) Aflatoxin (TLC) .....	115.00
(c) Corn oil, protein, and starch (one or any combination) .....	16.50
(d) Soybean protein and oil (one or both) .....	16.50
(e) Wheat protein (per test) .....	16.50
(f) Sunflower oil (per test) .....	16.50
(g) Vomitoxin (per test—qualitative) .....	39.00
(h) Vomitoxin (per test—quantitative) .....	44.00
(i) Vomitoxin (per test—HPLC Board Appeal) .....	134.00
(j) Pesticide Residue Testing <sup>3</sup> .	
(1) Routine Compounds (per sample) .....	207.00
(2) Special Compounds (per service representative) .....	106.00
(k) Fees for other tests not listed above will be based on the lowest noncontract hourly rate from Table 1.	
(iii) Review of weighing (per hour per service representative) .....	75.80
(3) Stowage examination (service-on-request) <sup>3</sup>	
(i) Ship (per stowage space) (minimum \$255.00 per ship) .....	51.00
(ii) Subsequent ship examinations (same as original) (minimum \$153.00 per ship).	
(iii) Barge (per examination) .....	41.00

TABLE 2.—SERVICES PERFORMED AT OTHER THAN AN APPLICANT'S FACILITY IN AN FGIS LABORATORY<sup>1 2</sup>—Continued

(iv) All other carriers (per examination) .....	16.00
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<sup>1</sup> Fees apply to original inspection and weighing, reinspection, and appeal inspection service and include, but are not limited to, sampling, grading, weighing, prior to loading stowage examinations, and certifying results performed within 25 miles of an employee's assigned duty station. Travel and related expenses will be charged for service outside 25 miles as found in § 800.72 (a).  
<sup>2</sup> An additional charge will be assessed when the revenue from the services in Schedule A, Table 2, does not cover what would have been collected at the applicable hourly rate as provided in § 800.72 (b).  
<sup>3</sup> If performed outside of normal business, 1½ times the applicable unit fee will be charged.  
<sup>4</sup> If, at the request of the Service, a file sample is located and forwarded by the Agency for an official agency, the Agency may, upon request, be reimbursed at the rate of \$2.50 per sample by the Service.

TABLE 3.—MISCELLANEOUS SERVICES<sup>1</sup>

(1) Grain grading seminars (per hour per service representative) <sup>2</sup> .....	\$52.50
(2) Certification of diverter-type mechanical samplers (per hour per service representative) <sup>2</sup> .....	52.50
(3) Special weighing services (per hour per service representative) <sup>2</sup>	
(i) Scale testing and certification .....	52.50
(ii) Evaluation of weighing and material handling systems .....	52.50
(iii) NTEP Prototype evaluation (other than Railroad Track Scales) .....	52.50
(iv) NTEP Prototype evaluation of Railroad Track Scales .....	52.50
(Plus usage fee per day for test car) .....	110.00
(v) Mass standards calibration and reverification .....	52.50
(vi) Special projects .....	52.50
(4) Foreign travel (per day per service representative) .....	475.00
(5) Online customized data EGIS service	
(i) One data file per week for 1 year .....	500.00
(ii) One data file per month for 1 year .....	300.00
(6) Samples provided to interested parties (per sample) .....	2.60
(7) Divided-lot certificates (per certificate) .....	1.50
(8) Extra copies of certificates (per certificate) .....	1.50
(9) Faxing (per page) .....	1.50
(10) Special mailing (actual cost)	
(11) Preparing certificates onsite or during other than normal business hours (use hourly rates from Table 1)	

<sup>1</sup> Any requested service that is not listed will be performed at \$52.50 per hour.  
<sup>2</sup> Regular business hours—Monday through Friday—service provided at other than regular hours charged at the applicable overtime hourly rate.

Dated: July 2, 2001.  
**David R. Shipman,**  
*Acting Administrator, Grain Inspection,  
 Packers and Stockyards Administration.*  
 [FR Doc. 01-17005 Filed 7-6-01; 8:45 am]  
**BILLING CODE 3410-EN-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

**Oral Dosage Form New Animal Drugs; Ivermectin and Pyrantel Pamoate Chewable Tablets**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Blue Ridge Pharmaceuticals, Inc. The ANADA provides for use of chewable tablets containing ivermectin and pyrantel pamoate for prevention of heartworm disease and for treatment

and control of certain gastrointestinal parasites in dogs.

**DATES:** This rule is effective July 9, 2001.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed ANADA 200-302 that provides for veterinary prescription use of Iverhart™ Plus (ivermectin and pyrantel pamoate) Flavored Chewables for Dogs for prevention of canine heartworm disease caused by *Dirofilaria immitis* and for treatment and control of ascarids (*Toxocara canis*, *T. leonina*) and hookworms (*Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*) in dogs. Blue Ridge's Iverhart™ Plus Flavored Chewables for Dogs is approved as a generic copy of Merial's Heartgart™ Plus Chewables, approved under NADA 140-971. ANADA 200-302 is approved as of May 30, 2001, and 21 CFR 520.1196 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**List of Subjects in 21 CFR Part 520**

Animal drugs.  
 Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to