

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b) <sup>2</sup>	353 <sup>5</sup>	1	353	24	8,472
606.100(c)	353 <sup>5</sup>	10	3,530	1	3,530
606.110(a) <sup>3</sup>	35 <sup>6</sup>	1	35	0.5	18
606.151(e)	353 <sup>5</sup>	12	4,236	0.083	352
606.160 <sup>4</sup>	353 <sup>5</sup>	793.20	280,000	0.75	210,000
606.160(b)(1)(viii)					
HIV consignee notification	2,000	10.50	21,000	.17	3,570
	4,980	4.21	21,000	.17	3,570
HCV consignee notification	2,000	23.40	46,800	.17	7,956
	4,980	9.4	46,800	.17	7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	349
606.160(b)(1)(ix)	2,081	840.94	1,750,000	0.05	87,500
606.160(b)(1)(xi)	2,000	3.375	6,750	0.05	338
606.165	353 <sup>5</sup>	793.20	280,000	0.083	23,240
606.170(a)	353 <sup>5</sup>	12	4,236	1.00	4,236
610.40(g)(1)	2,081	1	2,081	0.50	1,041
Total					362,426

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

<sup>2</sup>The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).

<sup>3</sup>The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).

<sup>4</sup>The recordkeeping requirements in §§ 640.3(a)(2) and (f); 640.4(a)(2); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b); 640.51(b); 640.53(b) and (c); 640.56(b) and (d); 640.61; 640.63(b)(3), (e)(1), and (e)(3); 640.65(b)(2); 640.71(b)(1); 640.72; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.

<sup>5</sup>Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 x 4,980 + 2,081).

<sup>6</sup>Five percent of plateletpheresis and leukopheresis establishments (0.05 x 696).

Dated: November 3, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0039]

#### Notice of Approval of Original Abbreviated New Animal Drug Application; Phenylbutazone Tablets

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for veterinary prescription use of phenylbutazone tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-433 providing for veterinary prescription

use of Phenylbutazone Tablets in horses for the relief of inflammatory conditions associated with the musculoskeletal system. First Priority, Inc.'s, ANADA for Phenylbutazone Tablets is approved as a generic copy of First Priority, Inc.'s, PRIBUTAZONE Tablets, approved under NADA 48-647. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514), in §§ 514.105(a) and 514.106(a), the Center for Veterinary Medicine is providing notice that this ANADA is approved as of October 23, 2008.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets

Management (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.

FDA has determined under 21 CFR 25.33(a)(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.

Dated: November 5, 2008.

**Bernadette Dunham,**  
 Director, Center for Veterinary Medicine.  
 [FR Doc. E8-26793 Filed 11-10-08; 8:45 am]  
 BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on

proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

or other forms of information technology.

**Proposed Project: Data Collection Worksheet Form (DCW): Reinstatement—(OMB No. 0915-0226)**

The Data Collection Worksheet Form for the National Health Service Corps Scholarship Program enables the Division of Applications and Awards/Scholarship Branch (DAA/SB) within the Health Resources and Services Administration (HRSA) to obtain the costs charged by each health professions training program for tuition, fees, and other reasonable educational expenses, in order to determine the amount of each scholarship award. The DAA/SB enters this information into its computerized data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Worksheet .....	650	1	650	0.5	325
Total .....	650	.....	650	.....	325

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 4, 2008.

**Alexandra Huttinger,**  
 Director, Division of Policy Review and Coordination.  
 [FR Doc. E8-26816 Filed 11-10-08; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; *telephone:* 301-496-7057; *fax:* 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**System for Correction of MRI Head Motion**

*Description of Technology:* Motion artifacts continue to be a significant problem in MRI of human brain. Prospective motion correction based on external tracking systems has been proposed to ameliorate this issue. However, the calibration of these systems is very complicated and time consuming, as it requires a camera system calibration as well as a calibration between camera and MRI system using dedicated phantoms. An alternative motion correction method for MRI that does not require calibration and can work with just a single video camera has been developed and is available for licensing. This technology can be broadly applied in MRI to account for motion artifacts in order to improve acquisition time and provide enhanced resolution. This technique will provide a needed method to obtain reliable MRI scans for uncooperative patients (children, seizure patients, etc.)