information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: July 15, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–19075 Filed 7–18–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Emergency Temporary Assistance for Needy Families Data Report.

OMB No.: New Request.

Description: This information is being collected to meet the statutory requirements of section 411 of the Social Security Act and section 116 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. It consists of disaggregated demographic and program information that will be used to determine participation rates and other statutorily required indicators for the Temporary Assistance for Needy Families (TANF) program.

Respondents: States, Puerto Rico, Virgin Islands, Guam and the District of Columbia.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF Data Report	54	4	451	97,416

Estimated Total Annual Burden Hours: 97,416.

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by September 1, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Driscoll at (202) 401–9313.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395–7316.

Dated: July 18, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–19068 Filed 7–18–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0215]

Babineaux's Veterinary Products, Inc., et al.; Withdrawal of Approval of NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of one new animal drug application (NADA) held by Babineaux's Veterinary Products, Inc., and two NADA's held by Schein Pharmaceutical, Inc. / Steris Laboratories, Inc. The sponsors requested voluntary withdrawal of approval of the NADA's because the products are no longer being marketed. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing those portions which reflect approval of these NADA's.

EFFECTIVE DATE: July 31, 1997

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION:

Babineaux's Veterinary Products, Inc., 6425 Airline Hwy., Metairie, LA 70003, is the sponsor of NADA 46–147 Dirocide (diethylcarbamazine citrate) Syrup. Schein Pharmaceutical, Inc. / Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705, is the sponsor of NADA 48–391 phenylbutazone injection and NADA 49–183 oxytocin injection. The sponsors requested withdrawal of approval of the NADA's under 21 CFR 514.115(d) because the products are no longer being marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 46–147, 48–391, and 49–183 and all supplements and amendments thereto is hereby withdrawn, effective July 31, 1997.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 510.600, 520.622b, 522.1680, and 522.1720 to reflect

withdrawal of approval of these NADA's.

Dated: July 11, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19065 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0107]

Determination of Regulatory Review Period for Purposes of Patent Extension; ProstaScint™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ProstaScint™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biologic product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product, ProstaScint™ (capromab pendetide). ProstaScint™ is indicated as a diagnostic imaging agent in newly-diagnosed patients with biopsy-proven prostate cancer, thought to be clinically-localized after standard diagnostic evaluation (e.g., chest x-ray, bone scan, CT scan, or MRI), who are at high-risk for pelvic lymph node metastases. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ProstaScint™ (U.S. Patent No. 5,162,504) from the Cytogen Corp., and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated April 10, 1997, FDA advised the patent and Trademark office that this human biologic product had undergone a regulatory review period and that the approval of ProstaScint™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ProstaScint™ is 2,561 days. Of this time, 1,906 days occurred during the testing phase of the regulatory review period, while 655 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: October 26, 1989. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 26, 1989.

2. *The date the application was initially submitted with respect to the human biologic product under section 351 of the Public Health Service Act*: January 13, 1995. The applicant claims January 12, 1995, as the date the product license application (PLA) for ProstaScint™ (PLA 94–0041) was initially submitted. However, FDA records indicate that PLA 94–0041 was submitted on January 13, 1995.

3. *The date the application was approved*: October 28, 1996. FDA has verified the applicant's claim that PLA 94–0041 was approved on October 28, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 353 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 19, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 20, 1998 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–19011 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F