

[Docket No. 95E-0046]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neurolite®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Neurolite® 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 drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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 drug product Neurolite®. Neurolite® (Technetium TC-99M Bicisate) single photon emission computerized tomography (SPECT) is indicated as an adjunct to conventional computed tomography (CT) or magnetic resonance imaging (MRI) in the localization of stroke in patients in whom stroke has already been diagnosed. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Neurolite® (U.S. Patent No. 5,279,811) from Dupont Merck Pharmaceutical Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 28, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Neurolite® 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 Neurolite® is 2,595 days. Of this time, 1,602 days occurred during the testing phase of the regulatory review period, while 993 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 18, 1987. The applicant claims September 18, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 18, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the human drug was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 6, 1992. The applicant claims March 5, 1992, as the date the new drug application (NDA) for Neurolite® (NDA 20-256) was initially submitted. However, FDA records indicate that NDA 20-256 was submitted on March 6, 1992.

3. *The date the application was approved:* November 23, 1994. FDA has verified the applicant's claim that NDA 20-256 was approved on November 23, 1994.

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 156 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 25, 1995, 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 November 22, 1995, 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: May 15, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-13033 Filed 5-25-95; 8:45 am]

BILLING CODE 4160-01-F

Health Resources and Services Administration

National Practitioner Data Bank; Change in Methods of Fee Payment

The Health Resources and Services Administration (HRSA), Public Health Service (PHS), Department of Health and Human Services (DHHS), is announcing a change in the method for payment of fees that are charged entities authorized to request information from the National Practitioner Data Bank (Data Bank).

The Data Bank is authorized by the Health Care Quality Improvement Act of 1986 (the Act), title IV of Public Law 99-660, as amended (42 U.S.C. 11101 et seq.). Regulations at 45 CFR Part 60 implementing the Data Bank authorize the reporting and release of information concerning: (1) Payments made for the benefit of physicians, dentists, and other

health care practitioners as a result of medical malpractice actions or claims; and (2) certain adverse actions taken regarding the licenses and clinical privileges of physicians and dentists. Section 60.3 of these regulations should be consulted for the definition of terms used in this announcement.

Section 427(b)(4) of the Act authorizes the establishment of fees for the costs of processing requests for disclosure and of providing such information. A final rule published elsewhere in this issue of the **Federal Register** amends the existing Data Bank regulations (45 CFR part 60) to remove regulatory restrictions on allowable methods of payment to permit the Secretary to announce alternate payment methods through periodic notice in the **Federal Register**. Section 60.12(c)(3) of the regulations states that the Secretary shall announce the method of payment of fees payable to the Data Bank through periodic announcement in the **Federal Register**. In determining the method, the Secretary shall consider efficiency, effectiveness, and convenience for the Data Bank users and the Department.

An assessment of the full operating costs related to processing requests for disclosure of Data Bank information as required by the DHHS Appropriations Act of 1994 (title II of Pub. L. 103-112, dated October 21, 1993), as well as the comparative costs of the various methods for filing and paying for queries has resulted in a decision to expand the options for methods of payment of Data Bank fees available to users.

Effective upon publication, the following methods of fee payment will all be accepted by the Data Bank: credit card, electronic funds transfer, check or money order.

Allowable methods of fee payment will be reviewed periodically and revised as necessary, based upon experience. Any changes in the methods of fee payment accepted, and the effective date of the change, will be announced in the **Federal Register**.

Dated: March 14, 1995.

Ciro V. Sumaya,
Administrator.

[FR Doc. 95-12908 Filed 5-25-95; 8:45 am]
BILLING CODE 4160-15-P

Public Health Service

RIN 0905-ZA91

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 New Drug Pricing

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of the following proposed guidelines relative to new drug pricing. Public comment is invited.

DATES: The public is invited to submit comments on the proposed guidelines by June 26, 1995. After consideration of the comments submitted, the Secretary will issue the final guidelines.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594-4353, FAX (301) 594-4982.

SUPPLEMENTARY INFORMATION: The Office of Drug Pricing has developed the following guidelines to facilitate program implementation:

New Drug Pricing

Calculation of the current quarter PHS ceiling price for each covered outpatient drug, as provided in section 340B(a)(1) of the PHS Act, is based upon data supplied to the Medicaid Drug Rebate Program (i.e., average manufacturer price, "AMP," and Best Price, "BP"). The manufacturer calculates pricing information for all of its covered outpatient drugs and sends this pricing data to the Health Care Financing Administration (HCFA) within 30 days after the end of the quarter. HCFA provides PHS with the data necessary for PHS to determine the ceiling price. PHS determines the ceiling price based on the rebate required under the Medicaid drug rebate program. For calendar year 1995, the Medicaid basic rebate for single source and innovator multiple source drugs is the greater of 15.2 percent of the AMP or the AMP minus best price. In calendar year 1996 and thereafter, the rebate percentage decreases to 15.1 percent. An additional rebate must also be paid for single source and innovator multiple source drugs in the amount by which the

increase in the AMP exceeds the increase in the Consumer Price Index—Urban (CPI-U). The PHS ceiling price is computed based on the combined basic and additional rebate amounts under the Medicaid program. For non-innovator multiple source drugs, the rebate percentage is 11 percent of the AMP.

For PHS pricing purposes, the timeframe for reporting the pricing data is a problem with respect to new drugs because there is a two quarter lag for new drug pricing information. For new drugs, AMP is not available until after the end of the first full quarter after the day on which the drug was first sold. For example, if a new drug was first sold on January 15, the AMP for the first full quarter would not be available until after June 30. Manufacturers would report the baseline AMP for this new drug to HCFA by July 31.

This time lag is not a problem for the State Medicaid agencies because they bill manufacturers for a rebate after the covered outpatient drugs are dispensed to Medicaid beneficiaries. However, to comply with the requirements of section 340B of the PHS Act, the PHS ceiling price must be determined before the covered outpatient drug is sold to the covered entity.

Because there is no sales data for a new drug from which to determine the PHS ceiling price, the Office of Drug Pricing is proposing to utilize a ceiling price estimated by the manufacturer until sufficient data is available to calculate the AMP and BP of the new drug. Any adjustments necessary to reconcile differences between the estimated and the actual ceiling price will be in the form of a retroactive charge back or rebate after the actual ceiling price is established.

Because the manufacturer calculates the PHS ceiling price using a two quarter data lag, the manufacturer could estimate the new drug ceiling price for three quarters. For example, a new drug that comes on the market in February (January–March quarter) will have an estimated PHS ceiling price for that quarter. AMP and BP data will be collected during the second quarter (April–June) and submitted to HCFA within 30 days after the third quarter (July–September) for calculation of the rebate percentage. Because pricing needs to be transmitted to wholesalers two weeks before the beginning of the quarter, an accurate PHS ceiling price for the third quarter will not be available at that time. The manufacturer must continue to estimate the PHS ceiling price for the second and third quarters, and will be able to calculate an accurate PHS ceiling price for the fourth