[Docket No. 91E-0036]

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

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: Food and Drug Administration (FDA) has determined the regulatory review period for Cardiolite® 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. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, 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 Cardiolite®. Cardiolite®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. Cardiolite® is also useful in the evaluation of myocardial function using the first pass technique. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Cardiolite® (U.S. Patent No. 4,452,774) from E.I. du Pont de Nemours and Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated February 21, 1991, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Cardiolite® represented the first commercial marketing 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 Cardiolite® is 1,660 days. Of this time, 920 days occurred during the testing phase of the regulatory review period, while 740 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 became effective:* June 7, 1986. The applicant claims May 7, 1986, as the date the investigational new drug (IND) application became effective. However, FDA records indicate that the IND effective date was June 7, 1986, which was 30 days after FDA's receipt of the IND application.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 12, 1988. The applicant claims February 22, 1988, as the date the new drug application (NDA) NDA 19-785 was filed. However, FDA records indicate that the NDA was received on March 17, 1988, and, was incomplete. FDA refused this application and notified the applicant of this fact by letter dated May 16, 1988. The completed NDA was then submitted on December 12, 1988.

3. *The date the application was approved:* December 21, 1990. FDA has verified the applicant's claim that NDA 19-785 was approved on December 21, 1990.

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 3.73 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 10, 1991, 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 October 7, 1991, 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.)

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: April 1, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-8254 Filed 4-8-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90P-0201]

RIN 0905-AA06

Print Size and Style of Labeling for Over-the-Counter Drug Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 5, 1991, the period for submission of comments on the notice on print size and style of labeling for over-the-counter (OTC) drug products. FDA is taking this action to allow interested persons time to consider Label Readability Guidelines, issued Ma

25, 1991, by the Nonprescription Drug Manufacturers Association (NDMA).

DATES: Written comments by August 5, 1991.

ADDRESSES: Submit written requests for single copies of NDMA's Label Readability Guidelines to the Division of Over-the-Counter Drug Evaluation (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send a self-addressed, adhesive label to assist that office in processing your requests. Submit written comments on print size and style of labeling for OTC drug products to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 6, 1991 (56 FR 9363), FDA issued a notice requesting comments on print size and style of labeling for OTC drug products. This notice provided an opportunity for public comment on a citizen petition filed by Pharmacists Planning Service, Inc., requesting regulatory standards for ıe print (optimum size and style) of /TC drug product labeling in order to maximize readability and legibility for persons with impaired or deteriorating vision. Interested persons were given until June 4, 1991, to submit comments on the notice.

On March 25, 1991, NDMA, a trade association of nonprescription drug manufacturers, issued Label Readability Guidelines that address many of the issues discussed in the agency's March 6, 1991 notice. Therefore, the agency is making available copies of NDMA's guidelines so that persons who wish to comment on FDA's March 6, 1991, notice may also consider NDMA's guidelines when making their comments.

The NDMA guidelines identify specific technical factors that can be addressed to improve the readability of OTC drug product labels. The guidelines cover major elements of readability pertaining to layout and design (e.g., design, layout and placement, hyphenation, uppercase/lowercase letters, paragraphs) and typography and printing (e.g., type size and style, contrast, printing process, color). The guidelines state that no single factor ר, of itself, determine readability; many factors interact, and the total effect of all factors must be considered.

The agency considers an extension of the time for comments to be in the public interest, so that a copy of NDMA's voluntary guidelines can be obtained by those persons who wish to review them before submitting comments. A copy of NDMA's guidelines is on public display between 9 a.m. and 4 p.m., Monday through Friday, in the Dockets Management Branch. Requests for single copies of the guidelines may be submitted to the Division of OTC Drug Evaluation (address above).

Interested persons may, on or before August 5, 1991, submit to the Dockets Management Branch (address above) written comments regarding right size and style of labeling for OTC drug products. Three 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 and may be accompanied by a supporting memoranda or brief. The information discussed above and any comments received may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 1991.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 91–8205 Filed 4–8–91; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–943–4214–10; GP1–173; OR–11304]

Opening of Lands; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This action will terminate the temporary segregative effect as to 15,560 acres of public and National Forest System lands included in a former application for withdrawal involving the Illinois Wild and Scenic River.

EFFECTIVE DATE: October 20, 1991.

FOR FURTHER INFORMATION CONTACT: Linda Sullivan, BLM, Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503–280–7171.

SUPPLEMENTARY INFORMATION: Pursuant to the regulations contained in 43 CFR 2310.2–1(e), at 8:30 a.m., on October 20, 1991, the following described lands will be relieved of the temporary segregative effect of former withdrawal application OR–11304:

Willamette Meridian

Those portions of the following described sections which constitute the bed or bank, or are within one-quarter mile of the bank, of the Illinois River:

T. 38 S., R. 8 W.,
Sec. 28.

Siskiyou National Forest

T. 38 S., R. 8 W.,
Secs. 7, 18, 19, 20, 29, 30, and 32.
T. 41 S., R. 8 W.,
Secs. 14 and 15.
T. 37 S., R. 9 W.,
Secs. 6, 7, 8, 16, 17, 20, 21, 28, 29, 32, and 33
T. 38 S., R. 9 W.,
Secs. 1, 2, 3, 4, 11, and 12.
T. 40 S., R. 9 W.,
Secs. 27 and 34.
T. 41 S., R. 9 W.,
Sec. 4.
T. 36 S., R. 10 W.,
Secs. 27 to 35, inclusive.
T. 37 S., R. 10 W.,
Secs. 1, 2, 3, and 12.
T. 35 S., R. 11 W.,
Secs. 17, 18, 19, 28, 29, 32, and 33.
T. 36 S., R. 11 W.,
Secs. 5, 6, 9, 16, 20, 21, 28, 29, 32, 33, 35, and 36.
T. 37 S., R. 11 W.,
Secs. 1, 2, 4, 5, 8, 9, 11, 12, 14, 15, and 16.

The areas described aggregate approximately 15,560 acres in Curry and Josephine Counties, Oregon.

Dated: March 28, 1991.

Robert E. Mollohan,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 91–8326 Filed 4–8–91; 8:45 am]

BILLING CODE 4310–33–M

[OR–943–4212–13; GP1–162; OR–15155]

Order Providing for Opening of Land; Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This action will open 82.36 acres of reconveyed land to surface entry and mining. The land has been and remains open to mineral leasing.

EFFECTIVE DATE: May 13, 1991.

FOR FURTHER INFORMATION CONTACT: Linda Sullivan, BLM, Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503–280–7171.

SUPPLEMENTARY INFORMATION: Under the reversionary provisions of the Recreation and Public Purposes Act of June 14, 1926, as amended (43 U.S.C. 869 et seq.), the following described land has been voluntarily reconveyed to the United States to be administered as