(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: January 18, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–1936 Filed 1–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0475]

Determination of Regulatory Review Period for Purposes of Patent Extension; Prandin (5,312,924)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Prandin 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Prandin (repaglinide). Prandin is indicated for use as an adjunct to diet and exercise to lower the blood glucose in patients with type 2 diabetes mellitus (non-insulin dependent diabetes mellitus) whose hyperglycemia cannot be controlled satisfactorily by diet and exercise alone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Prandin (U.S. Patent No. 5,312,924) from Dr. Karl Thomae GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 10, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Prandin 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 Prandin is 2,091 days. Of this time, 1,916 days occurred during the testing phase of the regulatory review period, while 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 355) became effective: April 3, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 3, 1992.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: July 1, 1997. The applicant claims June 27, 1997, as the date the new drug application (NDA) for Prandin (NDA 20–741) was initially submitted.

3. The date the application was approved: December 22, 1997. FDA has verified the applicant's claim that NDA 20–741 was approved on December 22, 1997.

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 747 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 29, 1999, 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 July 27, 1999, 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: January 18, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–1937 Filed 1–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0053]

Announcement of a Pilot Customer Satisfaction Survey: Medical Device Inspection Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 1-year pilot of a customer satisfaction survey entitled ''Medical Device Inspection Evaluation.'' The purpose of the evaluation is to provide a means whereby the medical device industry can provide feedback in an anonymous way to FDA's Office of Regulatory Affairs (ORA) regarding the medical device inspectional process. ORA intends to utilize a third party to collect the evaluations and trend the data submitted.

DATES: Written comments may be submitted at any time between March 1, 1999, through February 28, 2000.

ADDRESSEES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs, Division of Emergency and Investigational Operations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, e-mail ''ddion@ora.fda.gov''.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) has granted approval for this evaluation as a customer satisfaction survey. The evaluation is a followup to FDA/ORA's successful medical device industry initiatives, which included preannounced inspections, FDA 483 annotations, and postinspection notification letters. The Medical Device Industry Initiative Grassroots Taskforce, which includes members from industry and industry trade groups from across the nation as well as from FDA/ORA and FDA/Center for Devices and Radiological Health, is responsible for the design and development of this evaluation tool. The University of California-Irvine (UCI) Center for Statistical Consulting, Irvine, CA, is the third party that will collect and collate the evaluation forms and data. The data trends and findings will be made publicly available and will be shared with industry. The evaluation will be piloted for medical device preapproval, quality system/good manufacturing practices, and other related inspections.

The evaluation forms will contain preprinted information completed by the investigator regarding the name of the firm inspected, date of inspection, whether an FDA 483 was issued, the name of the investigator(s), the applicable FDA District Office and the reason for the inspection. The form will be accompanied by a preaddressed stamped envelope that is to be used to return the form to the UCI Center for Statistical Consulting (UCI). FDA expects the firm official with the most knowledge of the inspection to complete the industry survey portion of the evaluation as soon as possible after the inspection has ended. UCI will report the results by FDA District, FDA Region and nationwide.

The purpose of including investigator and firm identifiers on the evaluation is to assist UCI in obtaining clarifying information if needed and to determine the number of responses received versus the number of inspections conducted. FDA/ORA intends to share FDA's inspectional accomplishments (numbers) with UCI to help facilitate this determination of response rate. Neither the firm nor investigator identifier information will be entered into the data base or shared with FDA or industry.

The information collection provisions in this notice have been approved under OMB control number 0910–0360. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Interested persons may, at any time between March 1, 1999, through February 28, 2000, submit written comments to the Dockets Management Branch (address above). Two 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

BILLING CODE 4160–01–F

MEDICAL DEVICE INDUSTRY INITIATIVES TASK FORCE

MEDICAL DEVICE INSPECTION EVALUATION

This Section to be Completed by the FDA

Company Information

Company Name:

Company Address:

Telephone: ( ) Fax: ( ) E-mail:

Type of device(s) inspected:

Dates of Inspection: Start date: ____/____/____ (Month Day Year) End date: ____/____/____ (Month Day Year)

FDA Information

Name of lead investigator:

Number of supporting investigators:

FDA District (circle one): 1-NYK 2-NWE 3-PHI 4-BLT 5-NWJ 6-CIN 7-ATL 8-FLA 9-NSH 10-NOL 11-SJN 12-CHI 13-DET 14-MIN 15-DAL 16-KAN 17-DEN 18-SAN 19-LOS 20-SEA

Was a 483 issued?

1 YES
2 NO

Reason(s) for inspection (circle all that apply):

1 Pre-approval
2 QS/GMP
3 Other (please specify): _____

ALL FOLLOWING TO BE COMPLETED BY THE COMPANY

Definitions:

FDA 483 – FDA form issued to establishment management at the close of inspection if any problem(s) found.
EIR – Establishment Inspection Report
QS/GMP – Quality System/Good Manufacturing Practices

The first set of questions asks what happened before the inspection began. Please circle the number associated with the answer you choose. Your responses to all questions will be kept confidential.

Q-1 Did your company receive advance notification of the inspection?

1 YES → (If yes) How many days advance notification did you receive?
2 NO

_____ NUMBER OF DAYS

Q-2 During the pre-announcement phone call, did you have clarity of inspection requirements as to

a. Products 1 YES 2 NO
b. Records 1 YES 2 NO
c. Personnel 1 YES 2 NO

Q-3 Was it necessary to reschedule the proposed start of the inspection?

1 YES
2 NO

(If yes) Was the impact on your business

1 HELPFUL
2 NEUTRAL
3 DISRUPTIVE

The next set of questions asks about things that may have happened during the inspection.

Q-4 Was it necessary to interrupt the inspection for more than two working days?

1 YES
2 NO

(If yes) Was the interruption requested by

1 FDA
2 YOUR COMPANY

Characterize the impact of the interruption on your company

1 HELPFUL
2 NEUTRAL
3 DISRUPTIVE

Q-5 Were you able to have **all** the right personnel available during the inspection?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-6 Was your company able to meet **all** the needs of the investigator(s) for records availability?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-7 During the process of the inspection was your firm always notified daily of the investigator(s) observations?

1 YES
2 NO → PLEASE EXPLAIN:_____

Q-8 Did the investigator(s) provide any helpful information or suggestions?

1 YES
2 NO

The following questions pertain to the outcome of the inspection.

Q-9 Was an FDA 483 issued at the close of the inspection?

1 YES
2 NO → SKIP TO Q-18 ON THE BACK PAGE

Q-10 Were there any corrective actions taken or promised by your company during the process of the inspection? (CIRCLE **ALL** THAT APPLY)

1 YES, TAKEN
2 YES, PROMISED
3 NO, NEITHER → SKIP TO Q-14 ON THE NEXT PAGE

Q-11 Were there any corrective actions taken that were not verified by the FDA inspector(s) and you think could have been?

1 YES
2 NO
3 N/A, NO CORRECTIVE ACTIONS TAKEN

Please list the corrective actions taken which you believe could have been verified by the FDA inspector(s) but were not:

_____

Q-12 Have you already, or do you plan to fulfill any promised actions?

1 YES
2 NO
3 N/A, NO CORRECTIVE ACTIONS PROMISED

(If no) Have you advised the FDA of any changes in plans or delays?

1 YES
2 NO

Q-13 Were the promised or taken corrective actions appropriately annotated on the FDA 483?

1 YES, ALL WERE
2 SOME WERE, SOME WERE NOT
3 NO, NONE WERE

Please list whatever actions you believe were not appropriately annotated on the FDA 483:

_____

Q-14 Were there any inaccuracies on the FDA 483 **other than** those you may have described in Q-13 above?

1 YES
2 NO

(If yes) Were these inaccuracies on the FDA 483 corrected?

1 YES
2 NO → Please describe the situation(s): _____

_____

The final set of questions asks your evaluation of the inspection and about your company's actions.

Q-15 Were all of the observations on the FDA 483 understandable?

1 YES
2 NO → Please comment on what was not clear: _____

Q-16 Other than inaccuracies (noted in Q-14 above), were any of the observations on the FDA 483 inappropriate?

1 YES
2 NO

(If yes) Inappropriate items on the 483 were (CIRCLE **ALL** THAT APPLY):

1 INSIGNIFICANT OBSERVATIONS
2 DIFFERENCE OF INTERPRETATION
3 OTHER → Please explain:_____

Q-17 Do you plan to respond to the FDA 483 observations in writing?

1 YES
2 NO→ Please Explain: _____

Q-18 How did this inspection process compare with past inspections?

1 THIS WAS BETTER → Please explain:_____
2 SAME
3 THIS WAS WORSE → Please explain:_____
4 NEVER BEEN INSPECTED BEFORE

Q-19 Was the highest level executive in your facility in attendance at the final discussion with management?

1 YES
2 NO

Q-20 Worldwide, what is the total number of people your company employs in its medical device division(s)?

_____ NUMBER OF PEOPLE

Finally, we ask that you provide contact information should we need clarification about any of your responses. This is for the use by The UCI Center for Statistical Consulting *only* and will *not* be released to the FDA, to any industry group, or to anyone else.

Person Completing this Evaluation:

Name:

Title:

Telephone:

Fax:

We Invite Your Comments. We would like your suggestions concerning how the FDA inspection process could be improved. In particular, we would appreciate information concerning specific questions. If your comment pertains to a particular question number, it would be helpful if you would note the question number.

_____

_____

_____

_____

_____

_____

Thank you very much for your help!

Please return completed questionnaire to:

Anita Iannucci, Ph.D.
The UCI Center for Statistical Consulting
Social Science Plaza
University of California
Irvine, CA 92697-**5105**
(949) 824-1682 iannucci@uci.edu

Dated: January 21, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2014 Filed 1–27–99; 8:45 am]

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