Table 1 of supplemental web material (*http://www.sciencemag.org/features/data/1049221.shl*) that accompanied a report published in Science (Tracy, R.B., Hsieh, C.–L., & Lieber, M.B., ''Stable RNA/DNA hybrids in the mammalian genome: Inducible intermediates in immunoglobulin class switch recombination.'' Science 288:1058–1061, 2000; the ''Science paper''). In Table 1, Dr. Tracy misrepresented that lymphocytes from mice transgenic for ribonuclease H underwent significantly lower rates of isotope switching, as determined by the level of surface staining for immunoglobulin classes compared to control mice, when the actual data showed no such difference for IgG_1, IgG_{2b}, and IgE isotope classes. Dr. Tracy also falsified Figures 2 and 4 of the supplemental web material published with the Science paper in that the results were not representative of multiple independent experiments as he claimed. In addition, Dr. Tracy falsified Figure 2C of the Science paper, which represented a crucial control to establish his claim that RNA/DNA hybrids were limited to immunoglobulin switch regions, by publishing a blot that was not representative of his overall results.

Dr. Tracy also falsified Figures 4 and 7 of a second paper (Tracy, R.B., & Lieber, M.R. ''Transcription-dependent R-loop formation at mammalian class switch sequences.'' EMBO J. 19:1055–1067, 2000, ''EMBO J. paper''). In both figures, Dr. Tracy used the PhotoShop computer program to move bands or regions of a lane vertically relative to the rest of the gel, thus falsifying the size of molecules described in the paper. Lastly, Dr. Tracy reported these falsified data (as published in the Science and EMBO J. papers) in the progress report for NIH grant 5 R01 56984–03 in May 2000. Dr. Tracy and his coauthors retracted both the Science paper and the EMBO J. paper, in Science 289:1141, 2000, and in EMBO J. 19:4855, 2000, respectively.

Dr. Tracy has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of four (4) years beginning on May 1, 2002:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 CFR Part 76 (Debarment Regulations); and

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 02–12729 Filed 5–21–02; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0077]

Agency Information Collection Activities; Announcement of OMB Approval; Emergency Medical Device Shortage Program Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Emergency Medical Device Shortage Program Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 2002 (67 FR 13788), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0491. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12783 Filed 5–21–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1344]

Determination of Regulatory Review Period for Purposes of Patent Extension; COMTAN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COMTAN 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3565.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 COMTAN (entacapone). COMTAN is indicated as an adjunct to levodopa/carbidopa to treat patients with idiopathic Parkinson's disease who experience the signs and symptoms of end-of-dose ''wearing-off.'' Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for COMTAN (U.S. Patent No. 5,446,194) from Orion Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 17, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of COMTAN 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 COMTAN is 2,937 days. Of this time, 2,281 days occurred during the testing phase of the regulatory review period, while 656 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 (the act) (21 U.S.C. 355(i)) became effective*: October 6, 1991. The applicant claims November 29, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 6, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: January 2, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for COMTAN (NDA 20–796) was initially submitted on January 2, 1998.

3. *The date the application was approved*: October 19, 1999. FDA has verified the applicant's claim that NDA 20–796 was approved on October 19, 1999.

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 416 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 22, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 18, 2002. 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 (see **ADDRESSES**). Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02–12784 Filed 5–21–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01M–0478, 01M–0460, 01M–0454, 01M–0453, 01M–0452, 01M–0456, 01M–0451, 01M–0455, 01M–0578, 01M–0507, 01M–0579, 01M–0535, 01M–0462, 01M–0461, 01M–0536, 01M–0520, 01M–0439, 01M–0509, 01M–0490, 01M–0498, 01M–0479, 01M–0480, 01M–0482, 01M–0508, 01M–0522, 01M–0537, 01M–0523, 01M–0530, 01M–0531, 01M–0534, 01M–0567, 01M–0581]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page at http://www.fda.gov on the Internet, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act.