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