ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Study to Measure the Compliance of Prescribers With the Contraindication of the Use of Triptans in Migraine Headache Patients With Vascular Disease

Migraine headaches affect about 20 million Americans. Over the last decade, a category of drugs referred to as triptans, has been shown to be efficacious in treating migraine and has been prescribed to millions. However, triptans are routinely contraindicated in patients with vascular diseases due to associated rare occurrence of myocardial infarction, stroke, and other ischemic events. In view of the wide use of this class of drugs and the potential impact on public health, it would be of great use to better understand the prescribing practices as a result of this contraindication.

FDA plans to use the Internet to recruit triptan-user migraine headache patients to determine whether prescribers follow the labeling recommendation to avoid prescribing this class of drugs to patients with pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes or with cardiac risk factors. The study is intended to measure the proportion of patients that were prescribed triptans although they have pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes.

Soliciting patients over the Internet will identify a cohort of triptan users. These patients will then be asked to fill out a questionnaire about their medical history with a focus on vascular diseases. Following that, a sample of patients' medical records will be solicited and reviewed to verify the medical history. Prevalence of cardiovascular, cerebrovascular, or peripheral vascular ischemic diseases among migraine patients using triptans will be estimated. Information about patients' demographics, route of administration (oral, injection, intranasal), and duration of exposure to triptans will also be collected.

There are no available estimates about the rates of various vascular diseases and cardiac risk factors among migraine headache patients using triptans. The current study is considered a pilot study aimed at providing estimates of such rates to be used as a basis for future studies. Although FDA recognizes that the study population obtained through Internet-based recruitment may not reflect the population of triptan users at large, a signal of substantial prescribing to patients with vascular contraindications in this selected population may warrant further action on the sponsor's part to improve risk management. Improvement of risk management may include further study of the problem, a labeling change, educational programs performed by the sponsor, or increased restrictions on prescribing.

FDA estimates that approximately 500 persons will voluntarily complete the questionnaire. The estimated time for completing each questionnaire is approximately 2 hours, resulting in a total burden of 1,000 hours per year. The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
500	1	500	2	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Dated: November 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28581 Filed 11–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent application listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

High Efficiency Single Stranded Homologous Recombination in Host Cells Deficient for Mismatch Repair

Donald L. Court *et al.* (NCI); PCT Application No. PCT/US03/14657 filed 09 May 2003 (DHHS Reference No. E–038–2003/0-PCT–01); Licensing Contact: Norbert Pontzer; 301/435–5502; *pontzern@mail.nih.gov.*

Homologous recombination is the process of exchanging DNA between two molecules through regions of identical sequence. Homologous recombination provides an alternative to using restriction endonucleases and ligases for producing recombinant DNA. However, the background level of homologous recombination in *E. coli* is very low even with long homology arms. Previous improvements have provided methods of using bacterophage lambda Red recombination functions to greatly increase the recombination frequency of endogenous single- and double-stranded DNA with relatively short homology arms. This type of genetic engineering has been named ''recombineering,'' a convenient term to describe homology-dependent, recombination-mediated, genetic engineering. Recombination with endogenous linear single-stranded DNA (ssDNA) is likely to occur by annealing with transiently single-stranded regions of the chromosome such as the replication fork. We show that only the Beta component of the Red function is required for this activity. (Published PCT Application WO00/21449; Nat. Rev. Genet. 2001, 2:769–779.)

When the ssDNA used for recombineering introduces change(s) near the DNA replication fork, the change(s) may trigger mismatch repair (MMR), which in turn can reduce the level of recombination. In the present invention, altering MMR function achieves a 10-to 100-fold increase in Red recombination. This increase raises the number of recombinants to 25 to 30 percent of treated cells surviving electroporation of the oligo. Methods of transiently inhibiting MMR and bacterial strains deficient for the production of MMR genes are also provided. (Annu. Rev. Genet. 2002, 36:361–88.)

Dated: November 7, 2003.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 03–28657 Filed 11–14–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

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Automated Identification of Ileocecal Valve

Ronald Summers (NIHCC), Jianhua Yao (NIHCC), Daniel C. Johnson (Mayo Clinic); U.S. Provisional Application filed 10 Oct 2003 (DHHS Reference No. E–174–2003/0–US–01); Licensing Contact: Michael Shmilovich; 301–435–5019; *shmilovm@mail.nih.gov.*

Available for licensing is a system and software that analyzes digital representations of the colon and eliminates the occurrence of false positive colonic polyps. For example, in a scenario in which a list of polyp candidates is analyzed, the ileocecal valve can be removed from the list. Because the ileocecal valve is a normal structure and not a polyp (*i.e.*, a false positive), removing the ileocecal valve from the list of polyp candidates increases the usefulness and specificity of computer aided polyp detection techniques. Characteristics of a digital representation of at least a portion of a colon can be compared with paradigmatic characteristics of digital representations of ileocecal valves. Based on determining that the digital representation has the characteristics of an ileocecal valve, action can be taken. The digital representation can be removed from a list of polyp candidates or depicted distinctively in a visual depiction. Characteristics can include density, volume, intensity, attenuation, location within the colon, and the like.

Novel Non-Nucleoside Agents for the Inhibition of HIV Reverse Transcriptase for the Treatment of HIV–1

Christopher A. Michejda, Marshall Morningstar, Thomas Roth (NCI); U.S. Patent 6,369,235 issued 09 Apr 2002 (DHHS Reference No. E–076–1997/1–US–01); U.S. Patent Application No. 10/119,634 filed 09 Apr 2002 (DHHS Reference No. E–076–1997/1–US–02); Licensing Contact: Sally Hu; 301–435–5606; *hus@mail.nih.gov.*

Despite recent developments in drug and compound design to combat the human immunodeficiency virus (HIV), there remains a need for a potent, non-toxic compound that is effective against wild type reverse transcriptase (RT) as well as RTs that have undergone mutations and thereby become refractory to commonly used anti-HIV compounds. There are two major classes of RT inhibitors. The first comprises nucleoside analogues, which are not specific for HIV–RT and are incorporated into cellular DNA by host DNA polymerases. Nucleoside analogues can cause serious side effects and have resulted in the emergence of drug resistance viral strains that contain mutations in their RT. The second major class of RT inhibitors comprises non-nucleoside RT inhibitors (NNRTIs) that do not act as DNA chain terminators and are highly specific for HIV–RT. This technology is a novel class of NNRTIs (substituted benzimidazoles) effective in the inhibition of HIV–RT wild type as well as against variant HIV strains resistant to many non-nucleoside inhibitors. These NNRTIs are highly specific for HIV–1 RT and do not inhibit normal cellular polymerases, resulting in lower cytotoxicity and fewer side effects that the nucleoside analogues, such AZT. This novel class of compounds could significantly improve