certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA, and the estimates for the burden hours imposed by the following regulations are listed in table 1 of this document:

21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.

21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under 21 CFR 208.26.

21 CFR 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
208.20	8	1	8	320	2,560
314.70(b)(3)(ii) and 601.12(f)	2	1	2	72	144
208.24(e)	55,000	20	1,100,000	.0014	1,540
208.26(a)	1	1	1	4	4
Total					4,248

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

In the **Federal Register** of January 12, 2005 (70 FR 2174), FDA requested comments for 60 days on the information collection. No comments were received on this information collection.

FDA estimates that, on average, approximately 8 products annually would be classified as serious and significant and thus require Medication Guides. FDA's regulatory impact analysis estimated that applicants would require approximately 2 months of full-time effort (320 hours) to develop (i.e., develop for submission to FDA for review and approval) each Medication Guide. Based on an average annual professional labor cost of $70,000, the cost of developing each Medication Guide would be approximately $11,666 for a total cost of $93,328.

In addition, FDA estimates that the sponsor of one of the new or supplementary applications will request an exemption from at least some of the Medication Guide format or content requirements. FDA estimates that this will entail approximately 4 hours of work, or about $200.

In addition, FDA estimates that two existing Medication Guides annually might require minor change under 21 CFR 314.70(b)(3)(ii) or 21 CFR 601.12(f), necessitating 3 days (72 hours) of full-time effort per Medication Guide, for a total of 144 hours or $5,250.

Under section 204.24(e) authorized dispensers are required to provide a Medication Guide directly to the patient (or the patient's agent) upon dispensing a product for which a Medication Guide is required. Thus, the final rule imposes a third-party reporting burden on authorized dispensers, who, for the most part, will be pharmacists. FDA estimates that, on average, it would take a pharmacist approximately 5 seconds (.0014 hour) to provide a Medication Guide to a patient.

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11267 Filed 6–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0202]

Draft Guidance for Industry on Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bar Code Label Requirements—Questions and Answers.'' FDA regulations require certain human drug and biological products to have on their labels a linear bar code that identifies the drug's National Drug Code (NDC) number. We have received several inquiries about how the requirements apply to specific products or circumstances. The purpose of the draft guidance is to respond to the questions.

DATES: Submit written or electronic comments on the draft guidance by August 8, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For products regulated by the Center for Drug Evaluation and Research: Michael D. Jones, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

For products regulated by the Center for Biologics Evaluation and Research: Elizabeth Callaghan, Center for Biologics Evaluation and Research (HFM–370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3424.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bar Code Label Requirements—Questions and Answers.'' Under FDA regulations, certain human drug and biological product labels must have a bar code containing the drug's NDC number (69 FR 9120, February 26, 2004). Bar codes will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This draft guidance is intended to explain certain bar code labeling requirements and their application to human drug and biological products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on certain questions and answers on bar code labeling requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11266 Filed 6–6–05; 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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are 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 applications 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 applications.

Farnesyltransferase Inhibitors for Treatment of Laminopathies, Cellular Aging and Atherosclerosis

Francis Collins (NHGRI) *et al.*

U.S. Provisional Application No. 60/648,307 filed 28 Jan 2005 (DHHS Reference No. E–055–2005/0–US–01).

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov*.

Hutchinson-Gilford Progeria Syndrome (HGPS) is a very rare progressive childhood disorder characterized by premature aging (progeria). Recently, the gene responsible for HGPS was identified (Eriksson M, Brown WT, Gordon LB, Glynn MW, Singer J, Scott L, *et al.* Recurrent de novo point mutations in lamin A cause Hutchinson-Gilford progeria syndrome. Nature 2003; 423(6937): 293–8), and HGPS joined a group of syndromes—the laminopathies—all of which are caused by various mutations in the lamin A/C gene (LMNA). Lamin A is one of the family of proteins that is modified post-translationally by the addition of a farnesyl group. In progeria, the abnormal protein (progerin) can still be farnesylated, however, a subsequent cleavage is blocked.

The present invention describes a possible treatment of laminopathies, cellular aging and aging-related conditions such as HGPS through the use of farnesyltransferase inhibitors (FTIs) and other related compounds. This treatment should lead to a decrease in the accumulation of abnormal proteins such as progerin in case of HGPS patients and therefore reduce or eliminate many of the devastating clinical symptoms of the underlying biological defect of nuclear membrane instability (Goldman R, Shumaker DK, Erdos MR, Eriksson M, Goldman AE, Gordon LB, Gruenbaum Y, Khuon S, Mendez M, Varga R, Collins FS. Accumulation of mutant lamin A causes progressive changes in nuclear architecture in Hutchinson-Gilford progeria syndrome. Proc Natl Acad Sci U S A 2004; 8963–8968.).

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Cell Culture System for Efficient Expression of Self-Replicating Norwalk Virus

Kyeong-Ok Chang, Stanislav Sosnovtsev, Gael M. Belliot, Kim Y. Green (NIAID).

U.S. Provisional Application filed 08 Apr 2005 (DHHS Reference No. E–043–2005/0–US–01).

Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov*.

Available for licensing and commercial development is a cell culture system for the efficient expression of self-replicating Norwalk virus (NV) RNA (NV replicons). This invention provides compositions and methods for preparing a cell-based system for molecular studies of NV replication and the development of antiviral drugs. A method related to effectively clearing NV replicons, by subjecting cells infected with NV replicon to IFN-alpha is included that demonstrates the applicability of this invention to drug development. A method of effectively clearing NV replicons, by subjecting cells expressing the NV replicon to nucleotide analogues is also provided. These methods provide molecular tools for the identification and development of treatments for NV and may also extend to other members