I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling for Combined Oral Contraceptives.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for use for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for combined oral contraceptives (those that contain estrogen and progestin). This draft guidance incorporates changes in response to public comments on the previous draft guidance that was published in the **Federal Register** on July 10, 2000 (65 FR 42387). Because of the many changes resulting from comments on the 2000 draft, this guidance is being issued in draft again to allow for additional public input. Once comments on this second draft have been received and considered, the agency will finalize the guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on labeling for combined oral contraceptives. 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persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 25, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4886 Filed 3–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0137]

Guidance for Industry and Food and Drug Administration Staff; Surgical Masks—Premarket Notification Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Surgical Masks—Premarket Notification [510(k)] Submissions.'' This guidance is intended to assist industry in preparing premarket notification submissions for surgical masks.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Surgical Masks—Premarket Notification Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 15, 2003 (68 FR 26308), FDA announced the availability of a draft of this guidance document and invited interested persons to comment by June 16, 2003. FDA received four comments. The comments suggested various clarifications to the scope of the devices addressed by the guidance and to testing methods cited in the guidance, and other minor points. FDA revised the guidance to clarify these points.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on premarket notification submissions for surgical masks. 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 statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

IV. Electronic Access

To receive ''Surgical Masks—Premarket Notification Submissions'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381, or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (094) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters,

and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 25, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04–4982 Filed 3–4–04; 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.

Cloning and Characterization of an Avian Adeno-Associated Virus and Uses Thereof

Ioannis Bossis (NIDCR).

U.S. Provisional Application No. 60/472,066 filed 19 May 2003 (DHHS Reference No. E–105–2003/0–US–01).

Licensing Contact: Jesse S. Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

Currently, adeno-associated virus (AAV) represents the gene therapy vehicle of choice because it has many advantages over current strategies for therapeutic gene insertion. AAV is less pathogenic than other virus types; stably integrates into dividing and non-dividing cells; integrates at a consistent site in the host genome; and shows good specificity towards various cell types for targeted gene delivery.

To date, eight AAV isolates have been isolated and characterized, but new serotypes derived from other animal species may add to the specificity and repertoire of current AAV gene therapy techniques.

This invention describes vectors derived from an avian AAV. These vectors have innate properties related to their origin that may confer them with a unique cellular specificity in targeted human gene therapy. Therefore, vectors derived from this avian AAV are likely to find novel applications for gene therapy in humans and fowl.

This research has been described, in part, in Bossis and Chiorini (2003) J. Virol. 12:6799–6810.

Activation of Recombinant Diphtheria Toxin Fusion Proteins by Specific Proteases Highly Expressed on the Surface of Tumor Cells

Stephen Leppla, Shi-Hui Liu, Manuel Osorio, and Jennifer Avallone (NIDCR).

DHHS Reference No. E–331–2002/0–US–01 filed 06 May 2003.

Licensing Contact: Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov.*

This invention relates to diphtheria toxin fusion proteins comprising a diphtheria toxin (DT) cell-killing component and a cell-binding component such as granulocyte macrophage colony-stimulating factor (GM–CSF), interleukin 2 (IL–2), or epidermal growth factor (EGF). Receptors for the latter three materials are present on many types of cancer cells; therefore, these fusion proteins bind preferentially to these cancer cells. A key feature is that these toxins are altered so as to require activation by a cell-surface protease that is overexpressed on many types of cancers. Examples of such proteases include matrix metalloproteinases and urokinase plasminogen activator. Consequently, these novel cytotoxins kill tumors expressing receptors for either GM–CSF, IL–2, or EGF along with the cell-surface protease. Because killing requires the presence of both a receptor and a cancer-cell enriched protease, and few normal tissues contain both, there is less toxicity to normal cells. Thus, a larger amount of the agent may be used for cancer therapy without inducing side effects. In other words, these cytotoxins have a higher therapeutic index than toxins that are targeted to cells using a single strategy.

Dominant Negative Deletion Mutants of C-Jun and Their Use in the Prevention and Treatment of Cancer

NH Colburn, Z Dong, PH Brown, MJ Birrer (NCI).

U.S. Patent Application No. 08/213,433 filed 10 Mar 94 (DHHS Reference No. E–240–1993/0–US–01).

Licensing Contact: Jesse Kindra; 301/435–5559; *kindraj@mail.nih.gov.*

A number of mutants of the c-jun oncogene have been developed, which may be particularly useful in the prevention and treatment of cancer. Numerous studies have shown that tumor promotion is a long-term process that is partially reversible and that requires chronic exposure to a tumor promoter, and that subsequent progression of tumors through invasive and metastatic stages is also a long term process. In recent years, numerous cellular oncogenes have been implicated in the transactivation of genes associated with cellular growth and differentiation. One such cellular oncogene, c-jun, encodes a phosphoprotein that is a component of the dimeric transcriptional activator AP–1 along with c-Fos or other Jun or Fos family proto-oncoproteins. Several genes that may be involved in tumor promotion or progression have been shown to be dependent on AP–1 transactivation, including collagenase and stromelysin (transin). AP–1 inhibiting dominant negative deletion mutants of the c-jun gene have been developed that, when given to a mammal, may prevent or reverse carcinogenesis during early or late stages. For the treatment of cancer, a deletion mutant of the c-jun gene or the protein product may inhibit the elevated AP–1 transactivation that frequently characterizes tumor progression and may consequently prevent or reverse the development or further progression of