

for purposes of calculating a total burden under the Paperwork Reduction Act of 1995, only retirees and other

former employees are counted. The total cost to respondents is estimated at \$645.

Respondents	No. of respondents	No. of responses/re-spondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Former employees	86	1	0.25	21.5

Dated: February 24, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-6211 Filed 3-12-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing Grassroots Meetings for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two open public meetings: Registration and Listing Grassroots Meetings. The topic to be discussed at these meetings is FDA's intention to propose changes to the current medical device registration and listing system. These meetings are being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes manufacturers to register their establishments and list their devices, while ultimately reducing FDA's cost of

maintaining the registration and listing system.

DATES: See Table 1 in the "SUPPLEMENTARY INFORMATION" section of this document.

ADDRESSES: See Table 1 in the "SUPPLEMENTARY INFORMATION" section of this document.

FOR FURTHER INFORMATION CONTACT:

For general meeting program information: Bonnie H. Malkin, Office of Health and Industry Programs (HFZ-200), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-2845.

For registration information: Mark S. Roh, Pacific Region, Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612-5217, (FAX) 510-637-3977.

Those persons interested in attending these meetings, should fax their registration to 510-637-3977, including name and position/title, company name, mailing address, and telephone and fax numbers. There is no charge to attend these meetings, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Mark S. Roh at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Over the past one and a half years, FDA has reviewed the entire registration and listing process to determine if the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of

suggestions aimed at improving the registration and listing process for both FDA and industry. These meetings will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes.

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the World Wide Web (WEB). What are the advantages and disadvantages to industry and how would industry be affected if WEB submissions were mandated?

(2) Require that owners and parent companies register and list and take responsibility for the registration and listing of their establishments. What is the highest level in a company that should be responsible for registration and listing and how should this level be defined/described?

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), premarket approval, or product development protocol process.

(4) Because of the ease of submission through the WEB, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of the meetings will be available on the CDRH website approximately 15 working days after the meetings. The CDRH home page may be accessed at "http://www.fda.gov/cdrh".

TABLE 1.—MEETING SCHEDULES

Meeting Address	Dates	Times
Northern California Meeting Airport Hyatt, San Jose, 1740 North First St., San Jose, CA 95112, 408-993-1234.	Tuesday, April 20, 1999	Registration: 7:30 a.m. Meeting: 8:30 a.m. to 12 m.
Southern California Meeting FDA Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949-798-7714.	Wednesday, April 21, 1999	Registration: 7:30 a.m. Meeting: 8:30 a.m. to 12 m.

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-6265 Filed 3-12-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Listing of Members of the Food and Drug Administration's Senior Executive Service Performance Review Board

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the members of the FDA Performance Review Board (PRB). This action is intended to ensure that members of the PRB's are appointed in a manner that provides consistency, stability, and objectivity in performance appraisals, and that notice of the appointment of members of the board be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Arlene S. Karr, Office of Human Resources and Management Services (HFA-408), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4183.

The following persons will serve on FDA's PRB, which oversees the evaluation of performance appraisals of FDA's Senior Executive Service members in accordance with 5 U.S.C. 4314(c)(4):

Michael A. Friedman, Chairperson
Robert J. Byrd
Margaret J. Porter
Sharon Smith Holston
Linda A. Suydam

Dated: February 11, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 99-6267 Filed 3-12-99; 8:45 am]

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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 agencies 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 Joseph Hemby, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057 ext. 265; fax: 301/402-0220; e-mail: jh259b@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Novel ATP Binding Cassette Responsible for Cytotoxin Resistance

Michael C. Dean, Susan Bates, Tito A. Fojo, Rando Allikmets (NCI)
Serial No. 60/110,473 filed 30 Nov 98

This technology describes a new human gene (ABCP) that is a member of a subfamily that includes several multidrug resistance (MDR) transporters. It is highly expressed in placenta and is amplified 10-12 fold in the MCF ADVP3000 cells (mitoxantrone-resistant cells), but not in the SI-m1-0 (human colon carcinoma cells). The gene is important in the study of MDR and the development of drugs to block the transporter's function in MDR, as well as important in the role in placental function and fetal health. Mutations in this gene may predispose individuals to miscarriages or birth defects. The described technology may have utility as a diagnostic marker for drug resistance and drug screening for drugs that block the gene. The gene may also be a diagnostic marker for tumors of the breast and other tissues. Monoclonal antibodies to the ABCP gene are described in this technology. Also described are methods for overexpressing the ABCP gene in a cell. Protein and cDNA sequences of the ABCP gene are also disclosed.

Cloning and Characterization of Two Novel Human Factors, p52 and p75, That Mediate Transcriptional Activation and/or Pre-mRNA Splicing

Hui Ge (NICHD)

Serial No. 60/108,248 filed 13 Nov 98

This technology involves two novel, human transcriptional co-activators, p52 and p75 which are 52kd and 75kd polypeptides purified with Positive Co-

factor 4 (PC4) and are involved in the regulation of transcription. Mediation of transcription is extremely important since it is involved in almost every biological function. The co-activator, p52, has been implicated in pre-mRNA through interaction with Alternative Splicing Factor (ASF)/Splicing Factor 2 (SF2). Pre-mRNA splicing can generate multiple mRNAs for different proteins with different functions from a single gene, which is considered to be essential for the viability of many vertebrate organisms. These factors control and regulate gene expression of most genes and thus may have diagnostic, prognostic, and therapeutic utilities in the detection and treatment of many cancers and other genetic disease. The technology further describes the isolation of the cDNAs encoding the two transcriptional co-activators. The two co-activators share a region of 325 residues; however, they show distinct co-activator properties. Both co-activators interact directly with the VP16 activation domain and with components of the general transcription machinery. Sp1, a glutamine rich cellular activator which can bind the GC-box present in many cellular and viral promoters, is essential for the activation of the HIV-1 gene and others, requires the presence of the transcriptional co-activator p52. Thus, the technology may have a therapeutic utility in the prevention and therapy of AIDS.

Triplex Mediated Site Directed Mutagenesis

TA Winters, K Mezhevaya, I Panyutin, RD Neumann (CC)
DHHS Reference No. E-285-98/0 filed 08 Oct 98

This technology describes triple helix forming oligonucleotides (TFOs) which specifically bind to a target site in a DNA molecule to induce double strand breaks (DSB's). These TFO's are labeled with ¹²⁵I and are used to generate mutations at specific target sites. DNA DSB's are known to be highly mutagenic. Auger emitting radioisotopes such as ¹²⁵I are known to induce DNA DSB's when they disintegrate in close proximity to, or within the DNA duplex. In addition, radionuclides such as ¹²⁵I which emit ~20 Auger electrons upon disintegration would be expected to produce DSB sites that also contain base damage proximal to the strand break ends.

Potential applications of this technology include diagnostics or therapeutics where site specific mutagenic disruption or knock-out of target genes involved in genetic diseases such as cancer, HIV, human hepatitis B