

Dated: May 5, 1995.

Robert C. Livingston,

*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*

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**Product and Establishment License
Applications, Refusal To File;
Establishment of Refusal to File
Oversight Committee**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a standing oversight committee in the Center for Biologics Evaluation and Research (CBER) to conduct periodic reviews of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee will examine RTF decisions to assess consistency across CBER offices and divisions in RTF decisions and to determine whether the guidance currently available to sponsors needs to be revised.

ADDRESSES: Submit written requests for single copies of the CBER RTF guidance document to the Office of External Affairs, Industry Liaison Staff (HF-50), Food and Drug Administration, rm. 15-61, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-594-3074.

SUPPLEMENTARY INFORMATION: The importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority, as evidenced by initiatives, such as the following: (1) Procedures to expedite marketing approval for therapies for serious or life threatening illnesses (53 FR 41516, October 21, 1988; 57 FR 58942, December 11, 1992); (2) procedures and policies to make such therapies available prior to marketing approval through mechanisms such as the treatment investigational new drug (52 FR 19466, May 22, 1987) and the parallel track (57 FR 13250, April 15, 1992); (3) announcement of the availability of a CBER RTF guidance document for sponsors (58 FR 38770, July 20, 1993); and (4) implementation of a managed review process for PLA's,

ELA's, and supplements to PLA's and ELA's. The managed review process focuses on specific milestones or intermediate goals so that a quality review is conducted within specified time periods. The establishment and first meeting of CBER's RTF oversight committee, announced and described in this notice, continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

CBER recognizes that the practice of submitting incomplete or inadequate PLA's and ELA's and then providing additional information to FDA during an extended review period is inherently inefficient and wasteful of FDA resources. Such practice is also unfair to those sponsors who fulfill their scientific and legal obligations by submitting complete applications; the review of complete applications may be delayed while incomplete applications, submitted earlier, undergo review and repair.

By means of an RTF notification, CBER in general declines to file a sponsor's PLA or ELA because of omissions or inadequacies so severe as to render the application incomplete on its face. Although not a final determination, an RTF decision is a significant step that delays, at least for a time, full review of an application. CBER believes that an RTF decision is, in general, of benefit to sponsors as an early signal that the application has major deficiencies.

FDA regulations on filing PLA's and ELA's are found in §§ 601.2(a) and 601.3 (21 CFR 601.2(a) and 601.3). A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter the sponsor may ask that the application be filed over protest, similar to the procedure for drugs described under § 314.101(a)(3) (21 CFR 314.101(a)(3) (see 57 FR 17950, April 28, 1992)).

CBER has formed a standing RTF oversight committee, consisting of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions and to determine whether the currently available guidance provided to sponsors needs to be revised or supplemented.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available

because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, will be available from the FDA Chief Mediator and Ombudsman. If, following the committee's review, an RTF decision changes, the reviewing division will notify the sponsor of the change.

Dated: May 5, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-11827 Filed 5-12-95; 8:45 am]

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**International Scientific Conference on
Viral Safety and Evaluation of Viral
Clearance From Biopharmaceutical
Products; Public Meeting**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a meeting to discuss viral safety of biopharmaceutical products. FDA is cosponsoring the meeting with the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Department of Agriculture (USDA), the National Vaccine Program Office (NVPO), and the International Association of Biological Standardization (IABS). The meeting is intended to provide an exchange of information related to the viral safety of biological products, including information relevant to an International Conference on Harmonization (ICH) guideline on viral testing and validation that is presently under development.

DATES: The public meeting will be held on June 14 and 15, 1995, from 8:30 a.m. to 5 p.m., and on June 16, 1995, from 8:30 a.m. to 3:30 p.m. Participants may pick up their information packages and badges for admission to the sessions beginning at approximately 7:30 a.m. each morning.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 45, Main Auditorium of the Natcher Conference Center, 9000 Rockville Pike, Bethesda, MD. There is no registration fee for this meeting. Space is limited, and all interested parties are encouraged to register early (see the contact person listed below).

FOR FURTHER INFORMATION CONTACT:

For information regarding registration, housing, and other arrangements: Tammy Lowry, KRA Corp., 1010 Wayne

Ave., suite 850, Silver Spring, MD 20910, 301-495-1591, FAX 301-495-9410.

For other information: William Freas, Scientific Advisors and Consultants Staff (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, FAX 301-827-0294.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to present and discuss the available scientific evidence and experience relating to: Characterization of cell substrates for the presence of viruses, evaluation of virus removal and inactivation, and other issues relating to viral characterization. The symposium will discuss in detail topics related to the viral safety of biological products, including topics relevant to an ICH international guideline on viral testing and validation that is presently under development.

Plenary sessions will be held on the mornings of June 14, 15, and 16, 1995. Concurrent technical breakout sessions will be held on the afternoons of June 14 and 15, 1995.

Dated: May 9, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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Office of the Secretary

Grants and Cooperative Agreements; Availability, etc.: Managed Care Impact on People With Significant Physical and Mental Disabilities

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), Department of Health and Human Services (HHS).

ACTION: Request for applications to conduct research to better understand the impact of managed care on people with significant physical and mental disabilities. Projects will analyze existing data sets to explore issues of utilization, access, quality, costs and outcomes for people with disabilities in managed care systems. In addition, where possible proposed applications shall capitalize on linking state and local data sets containing data on functioning and health status for disabled individuals to utilization and cost data. For purposes of applications requested under this announcement, "individuals with disabilities" includes those under the age of 64 with ongoing conditions or chronic illnesses of such severity that they result in a need for extra or specialized health services or

assistance with daily living tasks. Specific groups of disabled individuals included in this definition are children and working aged adults 18-65 with physical disabilities, mental retardation, developmental disabilities and persistent mental illness.

SUMMARY: The primary goal of this grant announcement is to support research which employs the analysis of existing data and experience to inform policies related to disability and managed health care. Data sets which permit the Department to compare the service use, expenditures and outcomes of children and working age adults (18-64) with disabilities in managed care with similar persons in the fee-for-service system or that allow for an assessment of utilization and costs prior to and following managed care enrollment are of particular interest. Such data sets could include information from: Medicaid management information systems; community provider networks including community health centers; private insurers and health plans; employers; social security records; hospital records and other accessible data sets which contain relevant analytical variables. These projects are intended to foster new analyses of existing data sources by encouraging the use of data sets from states, local areas, or facilities in order to address issues of quality, cost, access and outcomes. We estimate that the scope and level of effort will require from 12 to 24 months to accomplish.

DATES: The closing date for submitting applications under this announcement is July 14, 1995.

ADDRESSES: Send application to Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, ASPE/IO, 200 Independence Avenue, SW., Room 405F, Hubert H. Humphrey Building, Washington, DC 20201. Attention: Albert A. Cutino, Grants Officer.

FOR FURTHER INFORMATION CONTACT: Application Instructions and Forms should be requested from and submitted to: Grants Officer, Department of Health and Human Services, ASPE/IO, 200 Independence Avenue, SW., Room 405F, Hubert H. Humphrey Building, Washington, DC 20201, Telephone: (202) 690-8794. Requests for Forms will be accepted and responded to up to 30 days prior to closing date of receipt of Applications. Technical questions should be directed to Andreas Frank or Kevin Hennessy, ASPE/IO, Telephone (202) 690-6443 or (202) 690-7272. Questions also may be faxed to (202)

401-7733. Written technical questions should be addressed to Dr. Hennessy or Mr. Frank at the above address. (Application submissions may not be faxed.)

ELIGIBLE APPLICANTS: The Department seeks applications from universities, post-secondary degree granting entities, managed care organizations, private employers and insurers, and other independent researchers. (For-profit organizations are advised that no grant funds may be paid as profit to any recipient of a grant or subgrant.) Profit is any amount in excess of allowable direct and indirect costs of the grantee.

SUPPLEMENTARY INFORMATION:

Part I

Legislative Authority

This cooperative agreement is authorized by Section 1110 of the Social Security Act (42 U.S.C. 1310) and awards will be made from funds appropriated under Public Law 103-112 (DHHS Appropriations Act for FY 1995).

Project History and Purpose

Rising health care expenditures have attracted considerable attention and concern over the past decade. Of particular concern to state and federal governments, Medicaid spending had increased from \$41 billion in 1985 to \$138 billion by 1994. In an effort to control spiraling Medicaid costs, states are increasingly turning to managed care, with estimates that approximately 25% of current Medicaid recipients are covered by a form of managed care, although participation remains concentrated in a relatively few states. With the demise of national health care reform this trend is expected to accelerate.

Over 93% of Medicaid payments are now made on a fee-for-service basis. Why is such a small proportion of Medicaid payments affected by the movement to managed care? An important reason is that about 70% of Medicaid expenditures goes to support the health care of the disabled and for long term care—neither of which is included in state managed care arrangements to any great extent.

Although research on the impact of managed care is still relatively new, studies of the public sector suggest that costs savings can be achieved without significant compromising quality. To beleaguered states trying to find ways to tame their Medicaid budget, the desire to incorporate their disabled and long term care populations under managed care is understandable.