

availability of a draft guidance for industry entitled "Cancer Drug and Biological Products—Clinical Data in Marketing Applications." The draft guidance document provides recommendations for sponsors designing clinical trials to demonstrate the safety and efficacy of cancer treatments on the collection of data that may be submitted to support marketing claims in new drug applications (NDA's), biologics license applications (BLA's), or applications for supplemental indications.

DATES: Submit written comments on the draft guidance by January 8, 2001.

General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the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 the office in processing your requests. The document may also be obtained by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Grant A. Williams, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5740, or Patricia Keegan, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications." This draft guidance provides general principles for data collection and submission for sponsors of investigational new drug applications, NDA's, BLA's, or applications for supplemental indications. It is intended to enable

sponsors to more effectively create plans to record and report the data from controlled trials that form the clinical basis for approval of anticancer drug and biological products.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on clinical data in marketing applications for cancer drug or biologic products. 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 written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any 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 Dockets Management Branch 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 <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statement of Mission, Organization, Functions and Delegation of Authority

Part G, of the statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, as amended at 60 FR 56606, November 9, 1995, and most recently amended at 61 FR 67048, December 19, 1996, is amended to reflect a reorganization of the Office of Public Health (GAB), Indian Health Service (IHS).

The changes are as follows:

Delete the functional statements for the Office of Public Health in their entirety and replace with the following:

Section GAB-00, Office of Public Health, IHS—Mission. The Office of Public Health, IHS defines its mission as a commitment to the well-being and cultural integrity of Indian people through a participatory and consultative process. The goal of the Office of Public Health is to elevate the health status of American Indian and Alaska Native (AI/AN) people to the highest possible level by (1) providing and/or assuring availability; (2) providing increasing opportunities for Indians to manage and operate their own health programs; and (3) serving as an advocate for Indian people.

Section GAB-10, Functions Office of Public Health (OOH) (GAB). (1) Advises and supports the Director, Indian Health Service (IHS), on policy, budget formulation, resource allocation regarding the operation and management of IHS direct, tribal, and urban public health programs, risk management, quality assurance, facilities programs, and self-determination; (2) provides agency-wide leadership and consultation to IHS direct, tribal, and urban public health programs on IHS goals, objectives, policies, standards, and priorities; (3) represents the IHS within the HHS and external organizations for purposes of liaison, professional collaboration, cooperative ventures, and advocacy; (4) manages and provides national leadership and consultation for IHS and Area offices on strategic and tactical planning, program evaluation and assessment, public health and medical services, research agendas, and special public health initiatives for the agency; (5) manages the design, development, and assessment for implementation of resource requirements and resource allocation methodology models for the agency; (6) manages demographic and program databases and performs statistical and epidemiological analyses and consultation; (7) carries out IHS responsibilities as required by the United States Federal Response Plan under Emergency Support Function No. 8; (8) assures agency compliance with the Code of Federal Regulations 45, Part 46, Protection of Human Subjects; and (9) manages and administers the functions related to business office services, contract health care, clinical and community services, preventive services, managed care, hospitals and ambulatory care centers, general public health practices and advocacy, environmental health, realty, facilities construction, facilities operation and

management, and environmental engineering.

Office of Executive Management (GAB-1). (1) Provides leadership and advice to the Director and public health programs on policy, budget, personnel, business office and the health care financing administration issues, and general administration; (2) represents the Director, Office of Public Health (OPH), in meetings with IHS employees and high-level management officials within the IHS, HHS, or other Federal agencies, tribes, and other organizations on administrative/management and policy issues. (3) participates with the National Council of Executive Officers, and meets with HHS/IHS leadership to provide agency advice on management and administrative matters; (4) administers, monitors, and assists in the development of office and program budgets and budget formulation; (5) manages and oversees the IHS third-party revenue generation activity; (6) participates in self-determination issues and processes pertaining to budget and tribal shares computation (7) functions as operational manager for administrative policies and activities within the OPH; and (8) provides guidance and carries out OPH responsibilities regarding Equal Employment Opportunities (EEO), labor relations, and other employee relations activities.

Administrative Management Team. (1) Provides program budget execution, analysis, and oversight; (2) provides guidance and coordinates the development and review of the OPH sections of the Department and Congressional budgets and presentation materials; (3) coordinates and assists in review of responses to budget inquiries and budgets materials for Congressional hearings and meetings; (4) coordinates, develops, promulgates, and maintains administrative policies, procedures, and manual issuances for the OPH; (5) monitors and administers existing agency administrative policies for OPH; (6) provides the OPH executive secretariat function; (7) serves as the review and coordinating point for OPH managed intra and interagency agreements; (8) serves as the principal resource for OPH personnel management and training issues consultation; (9) serves as the principal resource for OPH office space, property and supply activities; (10) serves as a general administrative resource for special activities/initiatives; and (11) provides direction and oversight on daily operations for the OPH.

Business Office Services Team. (1) Serves as the primary focal point for Business Office Services (BOS) program

operations and policy issues and represents BOS in national forums; (2) ensures improvement of the effectiveness and efficiency of the revenue generation activity, and provides support for local capacity building. (3) develops, disseminates, and maintains BOS policy and procedures manual (4) develops and promulgates standards and conducts BOS program reviews on a recurring, scheduled basis; (5) provides national leadership for Medicare, Medicaid, and private insurance reimbursement policy and procedures; (6) serves as the primary liaison with the Health Care Financing Administration for rate setting negotiations (7) serves as the focal point regarding Medicare and Medicaid managed care activities, including the review, evaluation, and monitoring of Sections 1115 and 1915(b) Medicaid waiver proposals and other State and Federal health care reform activities; (8) provides programmatic management of information systems for patient registration and billing and collections systems (9) assures training on various regulatory issues and negotiated managed care provider agreements; and (10) develops third-party budget materials and responds to congressional departmental inquiries regulating to third-party issues.

Office of Program Support (GAB-2). (1) Serves as a coordinating point for public health advocacy and as a source of technical support, development, and dissemination of policy advice for IHS Headquarters, OPH, Area offices, and facilities programs on the full scope of the public health and health data issues and activities; (2) serves as a resource and provides coordination and consultation to the IHS direct, tribal, and urban health programs (I/T/U) on public health issues; (3) provides and directs public health surveillance, intervention, research and evaluation programs, and the information systems to support them; (4) develops and coordinates agency strategic planning and performance measurement efforts with budgeting and requirements in consultation with OPH program staff; (5) provides consultation and coordination on the IHS budget formulation activity for planing and data purposes; (6) maintains, analyzes, makes accessible, and publishes results from national demographic and program databases; and (7) performs statistical and epidemiological consultation and coordination for the IHS in response to special conditions and communicable disease outbreaks of public health significance.

Office of Clinical and Preventive Service (GAB1). (1) Serves as the

primary source of technical and policy advice, and supports local capacity building for clinical and public health infrastructure for the IHS, Area offices, and I/T/U programs, on the full scope of clinical health care programs, including their quality assurance and preventive aspects, and tort claims; (2) provides leadership in articulating the clinical needs of the American Indian/Alaska Native (AI/AN) population and competing health care needs; (3) advocates the resource needs of specialized health care delivery providers of clinical services disciplines; (4) provides leadership, consultation and technical support to I/T/U public health programs; (5) develops, manages, and administers the program functions that includes, but are not limited to, behavioral health, chronic disease such as diabetes and cancer, dental services, emergency medical services, health records, maternal and child health, social services, pharmacy services, nursing services, nutrition and dietetics, laboratory, disabilities, and contract health care services; (6) investigates evidence-based and best practice models of service delivery for dissemination to community service locations; and (7) coordinates development of staffing requirements for new or replacement health care facilities and approves Congressional budget requests for staffing.

Division of Behavioral Health (GAB11). (1) Identifies industry program standards and monitors and evaluates community and Area-wide services provided through grants or contracts with Indian tribes, Indian organizations, and direct IHS operations in the area or mental health, social services, alcohol/substance abuse, and health education; (2) coordinates the Indian community behavioral health programs, such as alcoholism/substance abuse, mental health, social work, and health education with tribal program directors, division staff, Area line staff, and other agencies and institutions; (3) coordinates contracts and grants for behavioral health services and monitors services provides; (4) makes program and policy changes using data analysis, recommendations from operations levels, and research results. Coordinates resources allocation from program policies; (5) plans, develops, and coordinates a comprehensive mental health, social service, substance abuse and health education program and programs for children with special needs; (6) provides behavioral health program consultation to tribal groups and IHS staff; (7) provides leadership in

the identification of behavioral change interventions and supports implementations at the community level; (8) coordinates with State, Federal, professional, private, and community organizations on alternate health care resource; (9) provides leadership in measuring and evaluating the quality of behavioral health care services; and (10) prepares information on behavioral health for budgetary hearings, and program evaluation results for the IHS Director, the Congress, and the American people.

Division of Clinical and Community Services (GAB12). (1) Manages, develops, coordinates, and evaluates a comprehensive clinical and community program focusing on diabetes, maternal/child health, Indian children services, nutrition, AIDS, pharmacy, laboratory, health records, and health promotion and disease prevention; (2) develops and establishes standards for clinical and community services and special initiatives; (3) develops objectives, priorities, and methodologies for the conduct and evaluation of clinical and community health-based program; (4) provides, develops, and implements IHS guidelines, policies, and procedures on clinical and community based programs and initiatives; (5) monitors, evaluates, and provides consultation to clinical and community programs and new initiatives; (6) plans jointly with other agencies on research and coordinated services; (7) coordinates training needs and staff recruitment, assignment and development to meet service unit, area, and tribal needs; (8) provides increased awareness for health promotion and disease prevention and the maintenance of health; (9) coordinates and monitors contracts and grants with I/T/Us and other entities; (10) coordinates model diabetes program sites and provides support and direction to I/T/Us on diabetes related issues; (11) develops and disseminates information and materials to IHS facilities and (I/T/U); and (12) develops program budget materials and responds to congressional and department inquiries.

Division of Nursing Services (GAB13). (1) Manages the IHS Nursing Services, Women's Health, and Community Health Representative programs and advocates for program needs; (2) plans, develops, coordinates, and evaluates nursing and the community health representative program; (3) identifies and establishes standards for nursing services and the community health representative program; (4) provides leadership, professional guidance, and staff development; (5) plans, develops, coordinates, manages, and evaluates nursing education; (6) coordinates the

assignment and development of professional staff, including nursing recruitment staff, and scholarship recipients, to meet Service Unit, Area, and tribal needs in accordance with IHS policies and procedures; (7) provides guidance in planning, developing, and maintaining management information systems; and (8) prepares budgetary data, analysis and program evaluations and prepares information for program and budget presentations and congressional hearings.

Division of Oral Health (GAB14). (1) Plans, develops, coordinates, and evaluates dental health programs; (2) establishes staffing, procedural, facility, and dental contract standards; (3) coordinates professional recruitment, assignment, and staff development; (4) improves effectiveness and efficiency of dental programs; (5) develops resource opportunities and monitors utilization of resources for dental health programs; (6) formulates and allocates dental program budget; (7) advocates for oral health needs of AI/AN population; (8) coordinates health promotion and disease prevention activities for the dental program; and (9) monitors oral health status and treatment needs of the AI/AN population.

Division Contract Care and Risk Management (GAB15). (1) Plans, develops, and coordinates the Contract Health Service (CHS) program; (2) serves as the primary focal point for Contract Health Support (CHS) program operations and policy issues, and represents CHS in national forums; (3) develops, disseminates, and maintains CHS policy and procedures manual; (4) conducts CHS program reviews on a recurring, scheduled basis; (5) monitors the implementation of the IHS payment policy and reports the status to the Director, OPH; (6) administers the Catastrophic Health Emergency Fund; (7) administers the CHS Quality Assurance Fund; (8) administers the CHS claims adjudication activity for the IHS Headquarters; (9) administers the IHS fiscal intermediary contract and conducts data analysis; (10) coordinates the development of the CHS budget and the allocation of resources; (11) provides consultation to Headquarters and Area offices, and responds to inquiries from the Congress, tribes, and other Federal agencies; (12) serves as the primary source of technical and policy advice and consultation for IHS Headquarters and the OPH on risk management, quality assurance, and workers compensation; (13) manages the clinical features of tort claims against the IHS; (14) develops and disseminates clinical and personal risk management recommendations; (15) manages the IHS

workman's compensation claims; and (16) oversees IHS efforts in a variety of quality assurance and improvement activities.

Office of Environmental Health and Engineering (GAB2). (1) Serves as the primary source of technical and policy advice for IHS Headquarters and Area offices, tribal, and urban public health programs on the full scope of health care facilities, sanitation facilities construction (SFC) and management, environmental health, environmental engineering, clinical engineering, and realty services management; (2) develops objectives, priorities, standards, and methodologies for the conduct and evaluation of environmental health, environmental engineering, and facilities engineering and management activities; (3) coordinates the formulation of the IHS Facilities budget request and responds to all inquiries about the budget request and programs funded by the IHS Facilities appropriation; (4) maintains needs-based and workload-based methodologies for equitable resource distribution for all funds appropriated under the IHS Facilities appropriation; (5) provides leadership, consultation, and staff development to assure functional, safe, and well-maintained health care facilities, a comprehensive environmental health program, and the availability of water, sewer, and solid waste facilities for Indian homes and communities; and (6) coordinates the IHS responses to disasters and other emergency situations.

Division of Sanitation Facilities Construction (GAB21). (1) Develops, implements, and manages the environmental engineering programs including the SFC program, and compliance activities associated with environmental protection and historic preservation legislation; (2) provides agency-wide management assistance and special support/consultation to address special environmental public health problems, environmental engineering/construction activities and compliance with environmental legislation; (3) works closely with other Federal agencies to resolve environmental issues and maximize benefits to tribes by coordinating program efforts; (4) develops, implements, and evaluates agency program activities, objectives, policies, plans, guidelines, and standardized data systems for SFC activities; (5) consults with tribal groups/organizations in the development and implementation of SFC policies and initiatives, and in the identification of sanitation needs; (6) maintains a national inventory of current tribal sanitation facilities needs,

and past and present projects to address those needs; and (7) allocates financial resources nationwide based on need and workload using the national data inventories.

Division of Environmental Health Services (GAB22). (1) Develops, implements, and manages IHS Environmental Health Services programs including the Injury Prevention and Institutional Environmental Health programs, and serves as the primary source of technical and policy advice for IHS Headquarters and Area offices on the full scope of environmental health issues and activities; (2) maintains interagency relationships with other Federal agencies and tribes to maximize interagency and intertribal responses to environmental health issues and maximize benefits to tribes by coordinating program efforts; (3) provides leadership in identifying and articulating environmental health needs of AI/AN populations and support efforts to build tribal capacity; (4) provides personnel support services and advocates for environmental health providers; (5) maintains, analyzes, makes accessible, and publishes results from national data bases; (6) manages resource allocation activities in accordance with established criteria based on workload; (7) develops and evaluates standards and guidelines for environmental health programs and activities; and (8) performs functions related to environmental health programs such as injury prevention, emergency response, water quality, food sanitation, occupational health and safety, solid and hazardous waste management, environmental health issues in health care and non-health care institutions, and vector control.

Division of Facilities Operations (GAB23). (1) Develops, implements, and manages the programs affecting health care facilities operations, including routine maintenance and improvement (M&I), quarters, realty, and clinical engineering programs; (2) develops, implements, monitors, and evaluates agency program activities, objectives, policies, plans, guidelines, and standardized data systems for health care facilities operations; (3) serves as principal resource for coordination of facilities operations and provides consultation to IHS and the tribes on health care facilities operations; (4) maintains realty and quarters management systems; (5) maintains clinical engineering management systems; (6) formulates financial resources allocation methodologies nation-wide based on need and workload data; (7) maintains nation-

wide data on Federal and tribal facilities for program budget justification; and (8) develops and evaluates technical standards and guidelines for health care facilities operations.

Division of Facilities Planning and Construction (GAB24). (1) Develops, implements, and manages IHS Health Care Facilities Planning and Construction program, including the facilities planning process, facilities design process, facilities acquisition, and construction project management; (2) develops, implements, monitors, and evaluates agency program activities, objectives, policies, plans, guidelines, and standardized data systems for health care facilities planning and construction; (3) develops and maintains construction priority systems and develops project budget documents for the health care facilities construction program; (4) serves as the principal resource in providing leadership, guidance, and coordination of health care facilities engineering activities for the IHS Headquarters, Area offices, and I/T/Us; (5) monitors construction activities and the improvement, alteration, and repair of health care facilities; and (6) develops and evaluates technical standards and guidelines for health care facilities construction.

Division of Engineering Services (Dallas, Seattle) (GAB25). (1) Administers health care facilities engineering and construction projects for specified Area offices and administers the engineering and construction of certain projects for other Federal agencies through interagency agreements; (2) carries out management activities relating to IHS-owned and utilized health care facilities, including construction, contracting, realty, and leasing services; (3) serves as the source of engineering and contracting expertise for assigned programs/projects and other technical programmatic areas affecting the planning, design, alteration, leasing, and construction of IHS health care and sanitation facilities for Indian homes and communities; (4) assists in the development of Area office annual work plans, and in studies, investigations, surveys, audits, facilities planning, and technical standards development, related to IHS tribal health care facilities.

Section GAB-20, Office of Public Health—Delegations of Authority. All delegations and redelegations made to officials in the Office of Public Health that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further redelegation.

This reorganization shall be effective on the date of signature.

Dated: October 13, 2000.

Michael H. Trujillo,

Director, Assistant Surgeon General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Administrative Reporting Form (ARF) for the Women, Co-occurring Disorders and Violence Cooperative Agreement Program (Phase II)—New—The Women, Co-occurring Disorders, and Violence Study is funded by SAMHSA's Center for Substance Abuse Treatment (CSAT), Center for Substance Abuse Prevention (CSAP), and Center for Mental Health Services (CMHS) to produce knowledge on the development and effectiveness of integrated services for women with co-occurring mental health and substance abuse disorders who are victims of violence. Fourteen sites were funded in Phase I, and ten sites are expected to be funded in Phase II. During Phase I of the study (2 years), sites developed integrated service models. In Phase II, sites that successfully reapplied will test their interventions in a multi-site outcome study contrasting comprehensive, integrated, trauma-specific and Consumer/Survivor/Recovering Person (C/S/R) involved services to services as usual.

The Administrative Reporting Form (ARF) is a program monitoring instrument which is to be completed jointly by the project director, project staff members, and directors of participating organizations at each study site annually. The ARF collects information about the staffing and governance of each project, project accomplishments in the previous year, and specific project components.

Information collected with the ARF will be used in three ways. First, evaluators will use information from the ARF to describe the process of project