

readiness, deployments, and retirement; (5) provides PHS-related training to managers, supervisors, and PHS officers; (6) leads recruitment and retention efforts for staffing positions with PHS officers and champions diversity and inclusion efforts; (7) manages and administers the Commissioned Corps promotion and awards programs; (8) collaborates with CCHQ on deployments, manages agency deployments, oversees the Emergency Operations Center (EOC) Commissioned Corps deployment desk during activation of the EOC; and (9) plans, directs, and manages the Department of Defense's Eligibility Enrollment Report System identification card program for all active duty officers, retirees, and eligible dependents.

Benefits and Employee Services Office (CAJQN). (1) provides leadership, technical assistance, guidance, and consultation on work-life programs, pay, overseas allowances, retirement benefits, leave and benefits administration, on-the-job injuries and exposures to infectious diseases, debt complaints and other job-related issues; (2) coordinates and processes garnishment, child support, and other collection actions for employees; (3) provides technical advice, consultation, and training on matters of employee conduct and performance; (4) provides consultation, guidance, and technical advice to HR specialists, managers, and employees on the development, coordination and implementation of all payroll, benefits, retirement and worker's compensation initiatives; (5) provides personnel services relating to on-the-job injuries and exposures to infectious diseases; (6) facilitates the development and implementation of an agency-wide strategic approach to monitoring, evaluating, aligning, and improving benefits and employee services policies and practices; (7) provides HR services and assistance on domestic and international employee benefits, allowances and leave administration; (8) serves as liaison between CDC and the HHS payroll office resolving discrepancies with pay and leave; (9) administers the leave donor program and processes time and attendance amendments; (10) administers the Federal life and health insurance programs; (11) provides policy guidance and technical advice and assistance on retirement, the Thrift Savings Plan, health/life insurance, and savings bonds; (12) furnishes advice and assistance in the processing of Office of Workers' Compensation Program claims and the Voluntary Leave Donation Program; and (13) administers the

Veteran's Leave Program and processes the leave in the payroll system and coordinates with Technical Service Activity to update employee's record.

Office of the Director (CAJQN1). (1) provides leadership and overall direction for the Benefits and Employee Services Office; (2) develops goals and objectives, and provides leadership, policy formation, oversight, and guidance in program planning and development; (3) plans, coordinates, and develops strategic plans for the Benefits and Employee Services Office (BESO); (4) coordinates all program reviews; (5) provides technical assistance and consultation to the activities within BESO; (6) provides help desk support for BESO; and (7) coordinates, develops, and monitors implementation of program initiatives.

Retirement and Benefits Services Activity (CAJQN2). (1) provides HR services and assistance on domestic and international employee benefits, overseas allowances, and leave administration; (2) serves as liaison between CDC and the HHS payroll office resolving discrepancies with pay and leave; (3) audits payroll-related discrepancies regarding leave programs and processes time and attendance amendments; (4) administers the Federal life and health insurance programs; and (5) provides policy guidance and technical advice and assistance on retirement, the Thrift Savings Plan, health/life insurance, and savings bonds.

Compensation and Leave Administration Activity (CAJQN3). (1) provides consultation, guidance, and technical advice to human resources specialists, managers, and employees on the development, coordination and implementation of all Work Life program initiatives; (2) provides personnel services relating to on-the-job injuries and exposures to infectious diseases; (3) provides HR services and assistance on domestic and international employee benefits, overseas allowances; (4) furnishes advice and assistance in the processing of Office of Workers' Compensation Program claims; (5) furnishes advice and assistance in the processing of the Voluntary Leave Donation Program; (6) administers Veterans Leave Program and coordinates with the Technical Services Activity for record update; and (7) provides guidance on the FMLA.

Delegations of Authority

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further

redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Robin D. Bailey, Jr.,
Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023-14693 Filed 7-11-23; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reorganization of the Global Health Center

AGENCY: Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: CDC has modified its structure. This notice announces the reorganization of the Global Health Center (GHC). GHC reorganized to ensure optimal strategic planning and implementation of CDC's global health work to protect the United States and achieve global public health impact.

DATES: This reorganization was approved by the Director of CDC on June 28, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Thurmond, Office of the Chief Operating Officer, Office of the Director, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS TW-2, Atlanta, GA 30329. Telephone 770-488-4401; Email: reorgs@cdc.gov.

SUPPLEMENTARY INFORMATION: Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 88 FR 9290-9291, dated February 13, 2023) is amended to reflect the reorganization of the Global Health Center, Centers for Disease Control and Prevention. Specifically, the changes are as follows:

I. Under Part C, Section C-B, Organization and Functions, insert the following:

- Global Health Center (CW)
- Office of the Director (CW1)
- Division of Global HIV and TB (CWB)
- Office of the Director (CWB1)
- International Laboratory Branch (CWBB)
- HIV Prevention Branch (CWBC)
- HIV Care and Treatment Branch (CWBD)

- Maternal and Child Health Branch (CWBE)
- Epidemiology and Surveillance Branch (CWBG)
- Economics and Health Services Research Branch (CWBH)
- Overseas Strategy and Management Branch (CWBJ)
- Program Budget and Extramural Management Branch (CBK)
- Global Tuberculosis Prevention and Control Branch (CWBL)
- Science Integrity Branch (CWBM)
- Management and Operations Branch (CWBK)
- Strategy, Policy, and Communications Branch (CWBP)
- Special Initiatives Branch (CWBQ)
- Health Informatics, Data Management, and Statistics Branch (CWBR)
- Monitoring, Evaluation, and Data Analysis Branch (CWBS)
- Global Immunization Division (CWC)
- Office of the Director (CWC1)
- Polio Eradication Branch (CWCB)
- Accelerated Disease Control and Vaccine Preventable Diseases Surveillance Branch (CWCC)
- Immunization Systems Branch (CWCD)
- Strategic Information and Workforce Development Branch (CWCE)
- Division of Global Health Protection (CWD)
- Office of the Director (CWD1)
- Global Public Health Systems Branch (CWDB)
- Global Surveillance, Laboratory, and Data Systems Branch (CWDC)
- Global Workforce Development Branch (CWDD)
- Global Program and Extramural Management Branch (CWDE)
- Global Public Health Emergency Branch (CWDE)

II. Under Part C, Section C–B, Organization and Functions, retitle the following organizational units:

- Global Operations and Strategic Management Branch (CWEE) to the Global Program and Extramural Management Branch (CWDE)

III. Under Part C, Section C–B, Organization and Functions, delete the mission or functional statements for and replace with the following:

Global Health Center (CW). The Global Health Center (GHC) (1) leads the coordination and execution of CDC's global health country and regional programs, to achieve maximum public health impact in support of the agency mission; (2) works in partnership to assist ministries of health to build capacity, maximize public health impact and promote country ownership and sustainability; (3) achieves U.S. Government (USG) and international

organization goals to improve health, including disease eradication and elimination targets; (4) strengthens CDC's global health programs that focus on the leading causes of mortality, morbidity and disability and improves international capabilities through Global Health Security commitments to address public health emergencies and threats; (5) generates and applies new knowledge to achieve health goals; (6) strengthens health systems and their impact; and (7) ensures broad and specific investments in global health to promote USG commitments to protect health abroad and in the United States and meet public health emergency needs and health threats in international settings.

Office of the Director (CW1). (1) serves as the responsible authority for regional and country planning and cross-program integration, (2) harmonizes CDC global health priorities with host country priorities and those of regional entities, and works with ministries of health to improve essential public health functions, maximize positive health outcomes and promote country ownership and sustainability; (3) provides leadership, direction, and oversight, regardless of program affiliation, to all CDC country directors and regional directors in their role as a senior CDC representative with the U.S. Embassy and ministry of health and in implementing CDC's global health strategy in countries and across regional platforms; (4) provides coordination for CDC's global health security strategy, programs, policy and partnerships; (5) leads its divisions in implementing public health programs and ensures the impact and effectiveness of administration initiatives, congressionally-mandated programs and other public health programs; (6) measures the performance of CDC's global health programs in terms of public health impact and fiscal accountability; (7) provides leadership to promote growth and improvement of CDC global health programs; (8) provides scientific leadership in developing and implementing evidence-based public health interventions and promotes best scientific practice; (9) facilitates the conduct and maintenance of ethical and high-quality, scientific investigations by implementing regulatory requirements, monitoring human subjects compliance, and clearing scientific products; (10) works to strengthen surveillance systems to analyze, measure and evaluate the global burden and distribution of disease; (11) promotes scientific innovation and advances in global

health surveillance, epidemiology, monitoring and evaluation, and informatics; (12) harmonizes CDC's global laboratory activities to strengthen laboratory capacity globally and (13) promotes the introduction of innovative technologies and approaches to improve the diagnostic and screening capability of programs to better detect and respond to emerging pathogens; (14) participates in defining, developing, shaping and implementing U.S. global health policy and actions; (15) coordinates prioritization and planning for visits of high level officials to CDC and other strategic engagements; (16) provides leadership on issues management, budget formulation and performance integration for country-specific, regional, and geographic issues; (17) plans and executes CDC's internal and external global health communications strategy and public affairs media response/outreach in conjunction with CDC Immediate Office of the Director; (18) provides oversight, guidance, and accountability for all operations functions, human resources, workforce management, budget formulation and distribution, extramural reviews and processing, internal and domestic travel and property management responsibilities for the Center; (19) provides holistic operations support for all CDC workforce assigned overseas; (20) provides leadership and guidance in international hiring actions, including temporary assignments and liaison roles with international organizations, USG agencies, and related global institutes; (21) develops and maintains an effective global health workforce for CDC through strategic and innovative personnel solutions, policies and training initiatives, while demonstrating accountability for personnel resources and results of human capital investment; (22) provides leadership and guidance on informatics, information technology systems implementation, security, governance and planning for the Center and CDC's overseas presence; and (23) develops and ensures compliance with standardized management processes and solutions for CDC country offices and regional offices.

Division of Global Health Protection (CWD). The Division of Global Health Protection (DGHP) works to strengthen public health capacity globally to protect Americans and people around the world from health threats. DGHP helps to ensure global health protection and security through supporting the implementation of the International Health Regulations (IHR); developing and supporting in-country programs

including Field Epidemiology Training Programs and other public health workforce development programs, and the establishment or strengthening of national public health institutes (NPHIs); detecting emerging health threats; and by providing support to program and Center-led international public health emergencies, and agency-wide responses. DGHP works with partners to build strong, transparent, sustained public health systems through training, consultation, capacity building, and technical assistance in applied epidemiology, public health surveillance, policy development, informatics and health information systems, evaluation, implementation science, and laboratory systems. Specifically, DGHP: (1) works collaboratively across CDC and with external partners to provide country-based and international coordination for public health systems strengthening, disease detection, and IHR implementation; (2) provides support to build operational readiness and country capacity for robust functional public health leadership and coordination; and (3) provides resources and assists in developing country-level epidemiology, surveillance and data systems, laboratory, public health workforce and other core public health capabilities and partners with countries to support NPHIs as sustainable homes for public health preparedness and response to ensure country emergency preparedness and capacity to respond to outbreaks and incidents of local and international importance.

Office of the Director (OD) (CWD1). The DGHP OD provides leadership, management, and oversight for division activities. Specifically, the OD: (1) sets the broader strategy and priorities for the division in coordination with GHC and other program partners; (2) guides the implementation of the division's global health security program priorities and ensures activities align with agency goals and country priorities to support a "one-CDC" strategy; (3) develops and promotes partnerships with both national and international organizations, including other USG agencies, in support of division activities; (4) provides oversight and support to Regional Country Managers who provide programmatic leadership and technical supervision, and to branches who provide programmatic leadership to technical programs; (5) develops and implements risk management frameworks and identifies, analyzes, and develops strategies to prevent, manage, and respond to financial, legal, political, physical, and

security risks within the division; (6) ensures scientific quality, ethics, and regulatory compliance; (7) develops and coordinates division policy and communication strategies; (8) provides coordination of financial planning and liaises with GHC and the Office of Financial Resources on budget development and execution; (9) manages and coordinates division staffing, personnel, and resources; (10) manages monitoring and evaluation of division-supported activities to assess the effectiveness and impact of investments to support partner governments in building sustainable public health programs to address emerging health threats; and (11) provides support to program and Center-led international public health emergencies, and agency wide responses.

IV. Under Part C, Section C–B, Organization and Functions, add the following functional statements:

Global Public Health Systems Branch (CWDB). The Global Public Health Systems Branch (GPHSB) collaborates with government and key partners to establish or strengthen public health systems to ensure countries can quickly detect outbreaks and coordinate a national public health response. Specifically, GPHSB: (1) partners with countries to support the establishment or strengthening of NPHIs as sustainable homes for public health preparedness and response; (2) assists with the development of legal frameworks for NPHIs and operational plans for public health security, supports the operational readiness of NPHIs, and builds capacity for robust functional public health systems and leadership, including coordination of public health emergency response at national and sub-national levels; (3) partners with countries and supports regional collaborations to build operational capacity for public health response to ensure effective coordination and mobilization of resources during public health emergencies; (4) supports public health emergency management capacity building and systems strengthening of countries to facilitate implementation and enhance sustainable local, national and regional capacities, coordination and collaboration; (5) supports emergency management and response capacity building of CDC field staff and implementing partners; (6) measures country capacities to prevent, detect, and respond to infectious disease threats through existing evaluation frameworks such as joint external evaluations and State Party Self-assessment Annual Reporting and provide support for operational

planning to identify gaps within the 7–1–7 global health security framework; (7) strengthens public health partnerships to promote adherence to international health regulations; (8) identifies implementation strategies to support public health systems strengthening including primary care systems for health security, building on and leveraging strategic investments, and coordinates with appropriate subject-matter experts (SMEs) across GHC and other Centers, Institute, and Offices (CIOs); (9) promotes scientific innovation and advances implementation science to support the implementation of evidence-based public health interventions and rapid uptake of best practices; and (10) provides support to program and Center-led international public health emergencies, and agency-wide responses.

Global Surveillance, Laboratory, and Data Systems Branch (CWDC). The Global Surveillance, Laboratory, and Data Systems Branch (GSLDSB) focuses on building country capacity to address gaps in the modernization of disease-agnostic surveillance systems and supports building robust laboratory systems that are well integrated into public health systems and closely link epidemiology, laboratory, and surveillance systems to improve early detection of outbreaks. Specifically, GSLDSB: (1) provides oversight and accountability towards meeting agency global public health surveillance, laboratory and applied epidemiology objectives; (2) provides technical support on surveillance (event-based, early warning, indicator-based, integrated disease surveillance, etc.) to division field staff and supported countries; (3) increases health informatics capacities and supports data modernization and surveillance systems integration to improve early detection and effective use of data for public health action; (4) assists in the development and implementation of country national laboratory strategies and in close collaboration with other CIOs support capacities to strengthen early detection to outbreaks, especially of diseases of international public health concern; (5) provides technical assistance and scientific guidance to national public health entities in mapping laboratories in countries, assessing their diagnostic capacity for priority diseases, and supporting the establishment or strengthening of robust sample referral networks; (6) partners with CIOs and Offices to develop and conduct trainings based on international guidelines that facilitate the timely

transfer of newly emerging laboratory diagnostics and genomic applications, especially for public health action; (7) provides support, technical assistance, and trainings to promote biosafety, biosecurity, and global health laboratory quality standards and best practices, including through accreditations; (8) implements the Global Laboratory Leadership Program, which works to foster and mentor current and emerging leaders to build, strengthen, and sustain national laboratory systems; (9) identifies surveillance and laboratory implementation strategies building on and leveraging strategic investments, and coordinates with technical groups in GHC and global programs in other CIOs; (10) provides technical support for assessment, laboratory, surveillance, monitoring, applied epidemiology, and coordination during agency responses to public health emergencies; (11) promotes scientific innovation and advances implementation science to support implementation of evidence-based public health interventions and rapid uptake of best practices; and (12) provides support to program and Center-led international public health emergencies, and agency wide responses.

Global Workforce Development Branch (CWDD). The Global Workforce Development Branch (GWDB) plans and implements capacity-building competencies, science, and policy to support a robust public health workforce needed to strengthen countries' capacity to address public health threats at national, sub-national, and local levels. Specifically, GWDB: (1) partners with countries to develop and implement public health and emergency response workforce strategies that lead to sustainable improvements in time to detect, report, and respond to outbreaks, with an emphasis on field epidemiology, emergency response, health information, and bio-informatics; (2) implements the Field Epidemiology Training Program to support the development and sustainability of trained field epidemiologists in priority countries, with focus on foundational skills needed to collect, analyze, and interpret data to support evidence-based decision-making and inform timely public health action; (3) partners with other CIOs, international and regional organizations, and countries to develop and implement health information and bioinformatics workforce strategies that lead to sustainable improvements in time to detect, report, and respond to outbreaks; (4) supports building capacity of frontline health care workforce in countries using

standardized approaches to improve their skills to identify priority diseases and quickly respond to public health emergencies; (5) provides technical support to expand global public health workforce needed to stop outbreaks at their source in priority countries; (6) promotes scientific innovation and advances implementation science to support implementation of evidence-based public health interventions and rapid uptake of best practices in coordination with appropriate SMEs across GHC and other CIOs; (7) provides support to program and Center-led international public health emergencies, and agency wide responses; and (8) plans, implements, and evaluates training courses and workshops to strengthen in-country technical capacity in public health emergency situations in close coordination with relevant global programs and other CIOs.

Global Program and Extramural Management Branch (CWDE). The Global Program and Extramural Management Branch (GPEMB) provides cross-cutting coordination to support country-specific program planning, implementation, management, and oversight for division extramural functions, including grants, cooperative agreements, contracts, and interagency agreements. Specifically, GPEMB: (1) supports division headquarters and country staff to implement management and operations, and financial systems to effectively support public health systems that strengthen, advance, and protect health security, enhance health equity, and respond to public health emergencies; (2) facilitates program planning and implementation; fiscal and extramural management; personnel management; and administrative support in division country offices; (3) serves as a liaison between headquarters and the field to identify management and operations challenges, obstacles, and successes in implementing division activities in country offices; (4) executes effective program hiring, staffing requirements, oversight, and accountability for division in country offices in coordination with division branches, offices, and the OD; (5) in coordination with CIOs, facilitates and manages the development, cross CIO coordination of SME review, clearance, award, and close-out of all new and ongoing division headquarters and country program office grants, cooperative agreements, contracts, and interagency agreements; (6) provides oversight, monitoring, and facilitates reporting for all division grants, cooperative agreements, contracts, and interagency agreements; (7) supports agency efforts

during public health emergencies by coordinating, facilitating, and managing programmatic priorities and extramural functions in concert with GHC and other divisions; (8) promotes scientific innovation and advances implementation science to support implementation of evidence-based public health interventions and rapid uptake of best practices. In coordination with CIOs and global programs; and (9) provides support to program and Center-led international public health emergencies, and agency wide responses.

Global Public Health Emergency Branch (CWDG). The Global Public Health Emergency Preparedness Branch (GPHEPB) builds public health emergency management capacities to address global health security threats. Specifically, GPHEPB: (1) provides technical assistance and resources for public health disease surveillance, monitoring and evaluation, and applied epidemiology, in public health emergency settings in coordination with appropriate SMEs across GHC and other CIOs; (2) develops technical guidelines in collaboration with other CIOs on public health issues associated with international humanitarian emergencies; (3) plans and implements operational assessments aimed at developing the most effective public health interventions for populations in emergency settings in close coordination with relevant global programs and other CIOs; (4) supports strengthening strategic water, sanitation, hygiene monitoring, and intervention in collaboration with other CIOs in humanitarian settings; (5) liaises with international, bilateral, and non-governmental relief organizations involved with humanitarian emergencies; (6) promotes scientific innovation and advances implementation science to support implementation of evidence-based public health interventions and rapid uptake of best practices in coordination with global programs across GHC and other CIOs; and (8) provides support to program and Center-led international public health emergencies, and agency wide responses.

V. Under Part C, Section C–B, Organization and Functions, the following organizational units are deleted in its entirety:

- Office of the Associate Director for Global Health Coordination (CAE)
- Division of Parasitic Diseases and Malaria (CBBC)
- Workforce and Institute Development Branch (CBBEC)
- Global Operations and Strategic Management Branch (CBBED)

- Global Epidemiology, Laboratory, and Surveillance Branch (CWED)
- Global Operations and Strategic Management Branch (CWEE)

Delegations of Authority

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101)

Robin D. Bailey, Jr.,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–14706 Filed 7–11–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Income Withholding for Support Order (OMB No.: 0970–0154)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSS) (formerly the Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) to extend approval of the Income Withholding for Support Order (IWO), with minor changes, for an additional three years. The current OMB approval expires September 30, 2023.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The IWO is the required, standard form used to order, and notify, employers and income providers to withhold child support payments from an obligor's income. It is also used to notify employers and other income providers where to remit the payments, as well as other information needed to correctly withhold payments so that children and families receive the support to which they are entitled. On June 5, 2023, the Administration for Children and Families published a notice in the **Federal Register** (see 88 FR 36587) to announce a new official name for the former Office of Child Support Enforcement. As a result, all of the IWO instruments underwent revisions to change the “Office of Child Support Enforcement (OCSE)” to “Office of Child Support Services (OCSS).” The IWO form instructions underwent minor edits to clarify the language and OCSS augmented the instructions to include a sample form to improve the respondent's ability to properly complete the IWO Form. The burden estimates changed to reflect current estimates for the annual number of respondents and responses.

Respondents: Courts, private attorneys, custodial parties, or their representatives, employers, and other entities that provide income to noncustodial parents

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total annual number of respondents	Total annual number of responses per respondent	Average burden hours per response	Total annual burden hours
Income withholding order/notice (Courts, private attorneys, custodial parties or their representatives).	4,694,517	1	5 minutes	391,210
Income withholding orders/termination of employment/income status (Employers and other income providers).	1,277,952	8.01	2 minutes	341,213
Electronic income withholding orders/termination of employment/income status (Employers and other income providers).	33,746	67.70	30 seconds ..	19,038

Estimated Total Annual Burden Hours: 751,461.

Authority: 42 U.S.C. 666(a)(1), (a)(8), and (b)(6).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–14662 Filed 7–11–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2647]

Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled “Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development.” This draft guidance describes FDA's current recommendations for optimizing and standardizing dietary management in clinical trials for the development of drug products intended to treat inborn errors of metabolism (IEM) when dietary management is a key component of patients' metabolic control. Optimizing