Dated: December 9, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

[FR Doc. 2010–31386 Filed 12–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0616]

Draft Guidance for Industry on Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." This guidance is intended to assist sponsors in the codevelopment of two or more novel (not previously marketed) drugs to be used in combination to treat a disease or condition. This guidance provides recommendations and advice on how to address certain scientific and regulatory issues that will arise during codevelopment. The guidance is not intended to apply to development of fixed-dose combinations of already marketed drugs or to development of a single new investigational drug to be used in combination with an approved drug or drugs. The guidance is also not intended to apply to vaccines, gene or cellular therapies, blood products, or medical devices.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colleen Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm 4216, Silver Spring, MD 20993–0002, 301–796–1114.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination." The guidance is intended to assist sponsors interested in developing two or more novel (not previously marketed) drugs to be used in combination. Recent scientific advances have increased our understanding of the pathophysiological processes that underlie many complex diseases, such as cancer, cardiovascular disease, and infectious diseases. This increased understanding has provided further impetus for new therapeutic approaches that rely primarily or exclusively on combinations of drugs directed at multiple therapeutic targets to improve treatment response and minimize development of resistance. In settings in which combination therapy provides significant therapeutic advantages, there is growing interest in the development of combinations of investigational drugs not previously developed for any purpose.

Because the existing developmental and regulatory paradigm focuses primarily on assessment of the effectiveness and safety of a single new investigational drug acting alone, or in combination with an approved drug, FDA believes guidance is needed to assist sponsors in the codevelopment of two or more unmarketed drugs. This guidance is intended to describe a high-level, generally applicable approach to codevelopment of two or more unmarketed drugs. It describes the criteria for determining when codevelopment is an appropriate option, makes recommendations about nonclinical and clinical development strategies, and addresses certain regulatory process issues. The guidance does not apply to vaccines, gene or cellular therapies, or blood products.

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 companion diagnostic devices. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31426 Filed 12–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0618]

Statement of Organization, Functions and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized its Center for Tobacco Products (CTP) by establishing two new offices: Office of Health Communication and Education and the Office of Compliance and Enforcement. In addition, CTP has made improvements to the current offices' functional statements. This organizational change is intended to fill the gaps in the current CTP structure and clarify major responsibilities designed for long-term success in administering the Family Smoking Prevention and Tobacco Control Act.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Management; or Sharon Chartos, Office of Management, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–796–9200.

I. Introduction

The Statement of Organization, Functions and Delegations of Authority for the Center for Tobacco Products (74 FR 41713, August 18, 2009) is amended to reflect the restructuring of the Center for Tobacco Products that was approved by the Secretary of Health and Human Services on November 15, 2010:

II. Organization

The Center for Tobacco Products is headed by the Director and includes the following organizational units:

Center For Tobacco Products (DI)

1. Oversees the implementation of the Family Smoking Prevention and Tobacco Control Act, which provides FDA with several new authorities. These include restricting the marketing of tobacco products to minors; requiring new warning labels for cigarettes and smokeless tobacco products; prohibiting marketing measures that are misleading to consumers; establishing tobacco product standards; requiring Good Manufacturing Practice standards for tobacco product manufacturing facilities; requiring industry reporting of tobacco product ingredient and constituent data, including a description of the nicotine content and delivery mechanisms; educating the public and regulated industry about various provisions of the Family Smoking Prevention and Tobacco Control Act; and enforcement authorities including but not limited to enabling FDA to act quickly and effectively to remove products that are in violation of the statute.

2. Provides programmatic and policy direction to appropriate Center and Agency personnel on all matters related to implementation of the Family Smoking Prevention and Tobacco Control Act and identifies critical public health issues relating to tobacco product use.

3. Establishes and maintains effective relationships with senior FDA, Department of Health and Human Services (HHS), and Administration officials, industry representatives, Members of Congress, counterparts from State, local, territorial, and tribal governments, representatives from academia and public health organizations, and other key stakeholders on matters related to tobacco products.

Office of the Center Director (DIA)

1. Provides vision, leadership, and strategic direction for all Center activities related to regulation of tobacco products and implementation of the Family Smoking Prevention and Tobacco Control Act.

2. Provides vision, leadership, and strategic direction for all Center activities related to protecting the public health and communicating about the negative consequences of tobacco product use.

3. Plans, administers, coordinates, evaluates, and implements overall Center scientific, legal, policy, regulatory, compliance, public education, and management programs, policies, and plans.

4. Provides leadership and direction for Center management, planning, and evaluation systems to ensure optimum utilization of personnel, budgetary and financial resources, information technology, professional development, and facilities.

5. Establishes a program to maintain the highest levels of scientific quality and integrity for the Center.

6. Serves as the primary liaison and spokesperson on tobacco products regulation and the public health consequences of tobacco products use with FDA, HHS, Office of Management and Budget (OMB), the White House, Congress and the media, as well as with a variety of stakeholders, including regulated industry; tobacco control advocacy organizations; scientific, public health, and medical associations; academia; and State, local, territorial, and tribal governments.

7. Provides Center-wide program and strategic planning, execution, and support to Center leadership; coordination, development, clearance, and delivery of all Congressionally mandated reports, studies, and analyses; and also high quality briefing materials, background information for meetings, and speeches.

8. Provides correspondence control for the Center and controls and processes all public correspondence. Develops and operates executive correspondence tracking systems.

9. Manages the Center's Freedom of Information Act activities, coordinating responses with other Center technical, legal, regulatory, and policy units as well as developing direct responses.

10. Manages the Center's Ombudsman program.

11. Manages the Center's history program and archives.

Office of Management (DIB)

1. Provides authoritative advice and guidance to the Center Director on management policies, guidelines, issues and concerns that impact Center programs and initiatives.

2. Provides leadership, guidance, and direction regarding the development of long-range strategic management plans, operational plans, and systems for Center activities. Directs technical support staff in providing essential management services and other critical support functions.

3. Provides leadership and guidance as primary liaison with the FDA Office of Management to ensure provision of a broad range of essential technical support services.

4. Provides leadership and effective coordination as the primary Center liaison and expert with the Office of Information Management for provision and continuous improvement of information technology services to include networking, scientific computing software engineering, systems, and telecommunications.

5. Designs and develops performance management systems and operational/business process plans.

6. Analyzes management performance trends, FDA cost structure, and use of program resources.

7. Directs a variety of short-range and long-range special projects or assignments of substantial significance to the Center.

8. Administers and executes the Center management and fiscal planning and performance activities, budget formulation and execution, payroll, accounting, and property management functions.

9. Analyzes, formulates, and develops the annual budget for the Center in accordance with FDA, HHS, OMB, and Congressional guidelines. Provides oversight and ensures compliance with all regulations governing financial processes as outlined in FDA, HHS, OMB, and U.S. Government Accountability Office policies. Manages FDA, HHS, OMB, and Congressional inquiries regarding budget formulation and execution and required quarterly reports to Congressional Appropriations Committees.

10. Develops, maintains, monitors, analyzes, and reports data to Center management and program officials on the Center's budget/planning resource monitoring and evaluations systems.

11. Provides leadership within the Center to ensure compliance with statutes, executive orders, and administrative directives, such as the Chief Financial Officer Act and the

Federal Financial Managers' Financial Integrity Act.

12. Serves as the liaison between the CTP and the Bethesda Field Office, Atlanta Field Office, and/or Office of Management Programs on all personnel issues including, but not limited to, Human Capital Resources, appointment mechanisms, recruitment flexibilities, Senior Executive Service (SES) appointments, Title 42 appointments, retention flexibilities, and position management. Manages the Center's Performance Management program and the Center's Awards program.

13. Manages, tracks, and maintains the Center's regulatory submissions in accordance with FDA's records retention policies.

14. Receives, tracks, and stores all of Center's regulatory submissions.

15. Manages, conducts, and analyzes studies designed to improve Center processes and resource utilization and support requirements.

16. Manages facility-related activities for the Center including leases, space needs, maintenance, and development of architectural plans for move to FDA's White Oak campus.

17. Manages the Center's employee training and development activities, including individual employee development plans. Manages the Center's regulatory science fellowship program and other academic-based fellowship programs.

Office of Policy (DIC)

1. Advises the Center Director and other key Agency officials on public health, scientific, and regulatory policy development at the Center.

2. Develops and evaluates Center-wide priorities and policies, assuring FDA's statutory public health goals and policy needs are integrated into initiatives across science, regulations, compliance, public education, and management programs across the Center.

3. Ensures that Center policy decisions are consensus-based and informed, when relevant and appropriate, through communications with stakeholders in CTP, FDA, the Centers for Disease Control and Prevention, National Institutes for Health, HHS, and other government and relevant stakeholders and private agencies.

4. Monitors, coordinates, and advises the Center Director on policy involving sensitive, controversial, and complex issues related to Center activities that may involve precedent-setting matters or issues of particular concern to the Center Director or FDA Commissioner of Food and Drugs.

5. Analyzes and evaluates the impact and effectiveness of the Center's overall impact on public health.

6. Oversees public health policy and analytics; coordinates and conducts contingency analyses; manages special projects that require quick reaction/problem solving and planning; and develops and oversees the Center's approach to evolving issues in tobacco product regulation and control, such as impact on population health, development of policy aspects of tobacco product standards, modified risk products, substantial equivalence, and marketing and advertising.

7. Provides economic and modeling analyses on policy options as required.

8. Provides authoritative policy advice, guidance, assistance, interpretations, and recommendations to CTP, FDA, HHS officials, and scientific and professional personnel, intra-governmental counterparts (State, territorial and tribal officials).

9. Prepares and reviews legislative proposals, Congressional testimony; and materials related to implementing, amending, or modifying the Family Smoking Prevention and Tobacco Control Act, FDA laws, and regulations in collaboration with the Office of the Commissioner, Office of Legislation.

10. Provides advice and analysis for international tobacco control policies and acts as the Center's liaison with international stakeholders, including foreign governments.

11. Advises external stakeholders, including large and small tobacco manufacturers, tobacco control advocacy groups, medical and professional trade associations, State, territorial, local, and tribal governments, and others concerning the policy implications of the law and regulations.

12. Manages the Center's small business assistance activities.

Office of Regulations (DID)

1. Provides Center's oversight and leadership in, and coordinates the development of regulations, policies, procedures, and guidance related to the regulation of tobacco products.

2. Reviews and clears draft regulations developed by the Center, other FDA Centers, and other agencies.

3. Provides Center-level leadership and coordination for briefings within FDA, and with HHS, OMB, and other Federal agencies related to regulations and guidance documents.

4. Serves as the Center's focal point for developing and maintaining communications, policies, and programs with regard to regulations development, review, clearance, and publication.

5. Serves as the Center's primary liaison with the FDA's Office of Chief Counsel and the HHS Office of General Counsel; and provides support for legal defense in litigation.

6. Manages the development and implementation of plans for the Center's regulation development activities.

7. Provides technical assistance on the development of legislative proposals related to FDA responsibilities of the Family Smoking Prevention and Tobacco Control Act.

8. Manages the citizens' petition process on behalf of the Center.

9. Supports the Center in its regulatory litigation activities.

Office of Science (DIE)

1. Conducts scientific research and reviews programs to support the Center's goals for implementing the Family Smoking Prevention and Tobacco Control Act, as part of a comprehensive effort to reduce the toll of disease, disability, and death caused by tobacco products.

2. Serves as the focal point for overall management of Center activities related to science priorities and resources. Advises and assists the Center Director, FDA Commissioner of Food and Drugs, and other key officials on scientific issues that have an impact on public health, policy, direction, and long-range goals, and on the functions, capabilities, and management of scientific research facilities; and participates with other Agency components in planning such facilities.

3. Coordinates the Tobacco Products Scientific Advisory Committee which advises the Center Director, FDA Commissioner of Food and Drugs, HHS Secretary of Health and Human Services, and other key officials on certain issues related to the public health impact of tobacco products.

4. Organizes, plans, directs, and conducts research related to the development, manufacture, testing, labeling, and marketing of tobacco products in order to develop and maintain a scientific base for establishing policies, tobacco product standards, and test methods appropriate for the protection of public health.

5. Plans, directs, and conducts epidemiological research regarding the initiation, use, and cessation of tobacco products and the impact on the public health.

6. Coordinates targeted research to address Center priorities in collaboration with leading scientists in other segments of FDA, other Federal agencies, and the scientific community at large.

7. Plans, directs, and conducts research related to behavioral science, including consumer behavior and consumer perception of risks of harm from tobacco products.

8. Establishes and publishes a list of harmful and potentially harmful constituents in each regulated tobacco product.

9. Develops policies and procedures governing the submission and review of ingredient and constituent information for regulated tobacco products and oversees their implementation.

10. Develops and implements policies and procedures governing the submission and review of applications and postmarketing surveillance studies for modified-risk tobacco products.

11. Develops and implements policies and procedures governing the submission and premarket review of reports of substantially equivalent tobacco products and applications for new tobacco products.

12. Develops and implements policies and procedures governing submission and review of information regarding investigational tobacco products.

13. Develops, maintains, monitors, and analyzes policies, programs, and databases of adverse reactions to tobacco products.

14. Reviews, evaluates, and takes appropriate action on recommendations concerning denial or withdrawal of marketing and modified-risk authorizations for tobacco products.

15. Develops, in coordination with other Center offices, standards for Good Manufacturing Practices regarding methods, facilities, and controls for manufacturing, testing, and storage of tobacco products.

16. Participates, in coordination with other Agency components, in inspections of manufacturing facilities for compliance with applicable manufacturing and tobacco product standards.

17. Represents the Center in interactions with other government agencies, State and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on tobacco science and regulation issues.

18. Coordinates and provides guidance on science policy in program areas that cross major Agency component lines and on scientific aspects of critical or controversial issues, including Agency risk assessment policies.

Office of Health Communication and Education (DIF)

1. Serves as a comprehensive health communication enterprise developed as a part of a comprehensive effort to reduce the toll of disease, disability, and death caused by tobacco products.

2. Develops, coordinates, and evaluates public health communication and education activities in support of requirements of the Family Smoking Prevention and Tobacco Control Act.

3. Serves as the central point for communication about the Center's activities, campaigns, and key messages, including executing programs and implementing strategies about the regulation of tobacco products and the health risks associated with tobacco product use.

4. Ensures consistent branding, messaging, and strategic communications for all Center public education output.

5. Provides effective collaboration and coordination with partners and stakeholders on public health education and communications programs.

6. Provides accurate and timely public health information and education about tobacco products regulation and the requirements of the Family Smoking Prevention and Tobacco Control Act.

7. Develops and manages informational materials for health professionals and consumers, including Web pages and print media.

8. Manages Center's Web sites (Intranet and Internet).

9. Constructs risk communication messages in support of the requirements of the Family Smoking Prevention and Tobacco Control Act, using appropriate research methods.

10. Serves as the liaison between the Center and its stakeholders on public health education and communication programs.

Office of Compliance and Enforcement (DIG)

1. Advises the Center Director and other Agency officials on legal, administrative, and regulatory programs and policies concerning Agency compliance and enforcement responsibilities relating to tobacco products.

2. Coordinates, interprets, and evaluates the Center's overall compliance and enforcement efforts.

3. Provides technical support and guidance in the development and review of standards, regulations, and guidance related to compliance and enforcement.

4. Develops, directs, coordinates, evaluates, and monitors compliance and enforcement programs covering regulated industry.

5. Coordinates, develops, and directs State compliance and enforcement programs.

6. Provides training of Federal, State, and territorial compliance personnel.

7. Conducts field tests and inspections when necessary for regulatory purposes and evaluates regulated industry activities to assure compliance with regulations.

8. Provides advice to Agency field offices and commissioned officials, and manages Center activities relating to legal actions, case development, and contested case assistance.

9. Designs, develops, and implements Center programs to register tobacco establishments and product lists.

10. Coordinates all field planning activities and issues all field assignments for the Center.

11. Advises actual or potential manufacturers, distributors, retailers, and importers concerning the requirements of the law and regulations related to compliance and enforcement.

III. Delegation of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, or the Director of Center for Tobacco Products, all delegations and redelegations of authority made to officials and employees of affected organizational components in effect prior to this date will continue in effect in them or their successors, provided they are consistent with this reorganization.

Dated: December 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31383 Filed 12–14–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Intent To Request Approval From OMB of One New Public Collection of Information: Airport Federalization

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on a new Information Collection Request (ICR) (abstracted below) that we will submit to the Office of Management and Budget (OMB) for approval in compliance with the Paperwork Reduction Act (PRA). The