INTERAGENCY AGREEMENT
BETWEEN THE
FOOD AND DRUG ADMINISTRATION, HHS
AND THE
DEPARTMENTAL APPEALS BOARD, HHS

SCOPE FOR FDA-DAB IAA

FDA IAA: 224-15-90025 Mod 0003
DAB IAA # 16-DAB-FDACTP

1. Introduction and Overview

FDA plans to continue to utilize HHS Departmental ALJs and their support staff (*e.g.*, attorneys and paralegals) from the Departmental Appeals Board (DAB). The DAB ALJs and their support staff will act on behalf of FDA and will close out all cases which are filed with the DAB, as long as it is mutually agreeable to all parties.

1.1 Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations allow for several procedural avenues for which an ALJ is required or permitted, *e.g.*, 21 C.F.R. Parts 12, 16, and 17.

ALJ services will be required to adjudicate FDA's enforcement of violations related to tobacco products, as authorized by, the Family Smoking Prevention and Tobacco Control Act (FSPTCA), enacted on June 22, 2009, which amended the FD&C Act to provide FDA with the authority to regulate tobacco products. The FSPTCA provides for administrative actions, including civil money penalties (CMPs) and no-tobacco-sale orders (NTSO) to be assessed against violators of the Act's provisions related to tobacco products. *See* FD&C Act §§ 303(f)(8)-(9).

Regulations at 21 C.F.R. Part 17 set forth the practices and procedures for hearings concerning the administrative imposition of CMPs and NTSOs by FDA. *See* FD&C Act §§ 303(f)(8)-(9). The regulation requires that an ALJ qualified under 5 U.S.C. § 3105, preside over the entirety of the proceedings and be assigned to the case upon the filing of the complaint.

FDA's Center for Tobacco Products (CTP) is the component of FDA responsible for initiating all administrative actions related to tobacco product violations through FDA's Office of Chief Counsel.

This agreement will provide funding for the DAB ALJs to close out cases which were opened prior to October 1, 2016 as well as hear new cases filed with the DAB beginning on April 4, 2016.

1.2 Scope of Work (SOW)

The SOW includes all work performed by DAB ALJs and their support staff, as required to adjudicate administrative enforcement actions brought against violators of the FD&C Act.

1.3 Objectives

The DAB ALJs and their support staff shall act on FDA's behalf and provide the same functions to the FDA that is performed by the FDA Office of the ALJ to accommodate the high volume of cases.

1.4 Authority

Economy Act of 1932, 31 U.S.C. § 1535.

1.5 Projected Cost

Funding is requested for the salary and benefits of the ALJs and support staff, as well as any additional costs required for the full and proper adjudication of tobacco related cases by the DAB. The cost reflects the work that the DAB is performing for cases brought by CTP related to the regulation of tobacco products. Thus, the funding for such work will be through tobacco product user fee funds as required by Section 919 of the FD&C Act, 21 U.S. C. §387s, which requires that tobacco product user fees be used to pay for all tobacco regulation activities under Chapter 9 of the FD&C Act and the FSPTCA. 21 U.S.C. § 387s(c)(2)(B)(i). FDA will reimburse the DAB for all actual costs associated with ALJ review, conduct of hearings (*e.g.*, transcripts and travel), and administrative support (*e.g.*, attorney and paralegal work) in CTP cases.

Work that does not relate to tobacco product regulation is not covered under this Agreement. A separate funding agreement will be utilized to cover non-CTP work due to the prohibition on the use of tobacco user fees for non-tobacco regulation expenses. 21 U.S.C. §387s(c)(2)(A).

2. Requirements

The DAB ALJs and their support staff shall comply with all requirements of any applicable law or regulation related to the adjudication of matters brought before them, and the presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made. *See, e.g.*, 21 C.F.R. § 17.19.

2.1 Tasks

The DAB ALJs and support staff shall perform duties required for the adjudication of CTP proceedings opened with the DAB. Adjudications for CTP typically will be held under 21 C.F.R. Part 17 as it relates to CMP actions (*see* FD&C Act § 303(f)(9)) and NTSO actions (*see* FD&C Act § 303(f)(8)).

2.2 End Results/Deliverables

This Agreement will allow for the complete and proper adjudication of all proceedings open with the DAB in accordance with 21 C.F.R. Part 17.

3. **Transfer of Funds**

All transfers under this Agreement will refer to this Agreement and will reference the accounting information provided in the accompanying Form 7600B. Upon execution of this Agreement, FDA will make funds available to the DAB via the Intra-governmental Payment and Collection (IPAC) system. Request for transfers with supporting documentation for monies expended should be submitted on a quarterly basis. Contact Timothy Mueller at (301) 796-8775 and Timothy.Mueller@fda.hhs.gov for CTP billing questions.

4. **Duplication**

Full implementation of this Agreement will not duplicate any existing agreements.

5. **Privacy Act/Systems Security**

This Agreement is not subject to the Privacy Act.

George M. Warren -A

Digitally signed by George M. Warren -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300154429, cn=George M. Warren -A
Date: 2016.03.28 12:38:08 -04'00'

G. Matthew Warren Date
Director
Office of Scientific Integrity
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration

Constance B. Tobias 4/15/2016

Constance B. Tobias Date
Chair, Departmental Appeals Board
Office of the Secretary
Department of Health and Human Services

Georgine C. Delacruz 04/20/2016

Georgine C. Delacruz Date
Budget Analyst, Assistant Secretary for Financial Resources
Office of the Secretary
Department of Health and Human Services