SMG 1410.1103

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – TOBACCO

SUBSTANTIAL EQUIVALENCE AND PREMARKET REVIEW OF TOBACCO PRODUCTS

Effective Date: April 27, 2017

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to grant, deny, or rescind an exemption from the requirement of demonstrating substantial equivalence for a tobacco product under Section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, Center for Tobacco Products (CTP), Office of Medical Products and Tobacco (OMPT).

2) Director, Office of Science (OS), CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, Division of Product Science (DPS), OS, CTP, OMPT.

B. The following officials are authorized to determine that premarket review is required under Section 910(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, Division of Individual Health Sciences (DIHS), OS, CTP, OMPT.

C. The following officials are authorized to issue orders establishing whether a tobacco product is substantially equivalent under Section 910(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DPS, OS, CTP, OMPT.

D. The following officials are authorized to require that an application contain additional information and samples of tobacco product and components under Sections 910(b)(1)(E) and (b)(1)(G) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

E. The following officials are authorized to refer an application to the Tobacco Products Scientific Advisory Committee under Section 910(b)(2) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

F. The following officials are authorized to issue orders to approve or deny applications under Section 910(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

G. The following officials are authorized to deny applications and to provide information about the measures required to remove the application from deniable form under Sections 910(c)(2) and (c)(3) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

H. The following officials are authorized under Section 910(c)(5)(B) of the Federal Food, Drug, and Cosmetic Act to make determinations that there exists valid scientific evidence (other than the evidence set forth in Section 910(c)(5)(A)) which is sufficient to evaluate the tobacco product and may authorize that determinations for the purposes of Section 910(c)(2)(A) be made on the basis of such evidence:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

I. The following officials are authorized to propose to temporarily suspend and propose to withdraw orders issued under Section 910(c)(1)(A)(i) and under Section 910(d) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

J. The following officials are authorized to designate the employees who will serve orders issued under Section 910 of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

K. The following officials are authorized to issue orders prescribing the records and reports to be established and maintained for tobacco products and that reports be made to CTP under Section 910(f)(1) of the Federal Food, Drug, and Cosmetic Act:

1) Director and Deputy Director, CTP, OMPT.

2) Director, OS, CTP, OMPT.

3) Deputy Director for Research, OS, CTP, OMPT.

4) Deputy Director for Regulatory Science and Management, OS, CTP, OMPT.

5) Director and Deputy Director, DIHS, OS, CTP, OMPT.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on April 27, 2017.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	02/29/2012	N/a	OMPT/CTP/ OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	10/09/2014	N/a	OMPT/CTP/ OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	04/27/2017	N/a	OMPT/CTP/ OM	Stephen M. Ostroff, M.D. Acting Commissioner of Food and Drugs

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