RAI SERVICES COMPANY

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VIA HAND DELIVERY AND FAX

Centers for Disease Control and Prevention
Desk Officer, Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: Docket No. CDC-2019-01322 ("Agency Forms Undergoing Paperwork Reduction Act Review")

Dear Sir or Madam,

On February 7, 2019, the Centers for Disease Control and Prevention ("CDC") published a notice of information collection request ("Notice") in accordance with the Paperwork Reduction Act of 1995,[1] titled *Agency Forms Undergoing Paperwork Reduction Act Review*, 84 Fed. Reg. 29, 2525–26.[2] CDC's Office of Management and Budget ("OMB") seeks comments on its annual collection of composite lists of ingredients added to tobacco in the manufacture of cigarette products. Specifically, the OMB seeks comments about (a) whether its current information collection regime is "necessary for the proper performance of the functions of the agency," including whether the information collected has "practical utility[;]" (b) the accuracy of CDC's estimate of the burden of the proposed collection of information; (c) whether the proposal enhances "the quality, utility, and clarity of the information to be collected;" (d) "[m]inimiz[ing] the burden of the collection of information" on those required to produce it; along with (e) an assessment of "information collection costs."[3] In response, RAI Services Company ("the Company") respectfully submits these comments on its own behalf and on behalf of its affiliated tobacco companies.[4] The Company has provided CDC with the information at issue in the Notice since 1986, without issue and without objection, and will continue to do so should the current information collection regime remain intact. These comments are intended to address the inefficiencies of the current regime and offer a workable solution moving forward.

The comments are organized into three sections: an overview of the current information collection regime of the Department of Health and Human Services ("HHS"); a proposal that would

[1] Pub. L. 104-13, 44 U.S.C. §§ 3501 *et seq.*
[2] *See Agency Forms Undergoing Paperwork Reduction Act Review*, 84 Fed. Reg. 2525–26 (Feb. 7, 2019).
[3] *Id.* at 2526.
[4] RAIS performs regulatory compliance services for Reynolds American Inc.'s ("RAI") subsidiary companies, including R.J. Reynolds Tobacco Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., and R.J. Reynolds Vapor Company. RAI is an indirect, wholly owned subsidiary of British American Tobacco p.l.c. References to "the Company" in this letter may include activities undertaken by RAIS or by its affiliated RAI subsidiaries, as applicable.

satisfy reporting requirements and minimize the burden on the Federal Government and those required to report to it; and an assessment of CDC's estimation of the burdens associated with its request.

COMMENTS

I. THE CURRENT INFORMATION COLLECTION REGIME IS UNNECESSARILY REDUNDANT

CDC's efforts to collect cigarette ingredients have spanned over thirty years, beginning with the passage of the Comprehensive Smoking Education Act of 1984 (P.L. 98–474) ("CSEA"). Since then, the structure of HHS has drastically changed. In 2009, with the passage of the Family Smoking Prevention and Tobacco Control Act (P.L. 111-31, 21 U.S.C. §§ 387 *et seq.*) ("TCA"), the United States Food and Drug Administration ("FDA") was granted sweeping powers which include, *inter alia*, the power to collect extensive information and documentation related to tobacco products, and the power to regulate such products. CDC's duplicative and overlapping efforts, however, persist to this day.

CDC stated in the Notice that it is required to collect cigarette ingredient information under the CSEA, which amended the Federal Cigarette Labeling and Advertising Act (P.L. 89–92, 15 U.S.C. §§ 1331 *et seq.*) ("FCLAA"). However, as amended, the FCLAA requires reporting, not collection.[5] It requires tobacco product manufacturers to provide a list of ingredients added to tobacco in the manufacture of cigarette products to the Secretary of HHS.[6] The Secretary of HHS has delegated administration of that requirement to CDC.[7] Without that delegation, CDC has no obligation to collect the information. Furthermore, a separate tobacco manufacturer reporting requirement (to FDA) renders the delegation to the CDC duplicative.

Under Section 904 of the TCA, tobacco product manufacturers are required to submit detailed information to the Secretary of HHS regarding, among other things, the ingredients added to tobacco in their cigarettes.[8] The Secretary delegated enforcement of the TCA to FDA, an agency of HHS.[9] Section 904 of the TCA requires tobacco product manufacturers to submit "a listing of all ingredients, including tobacco substitutes, compounds, and additives that are" added to the "tobacco, paper, filter, or other party of each tobacco product by brand and by quantity" in each brand.[10] Additionally, upon request, manufacturers must submit documentation related to research activities and findings pertaining to, among other things, the health effects of tobacco products.[11] Moreover, unlike CDC, FDA has authority to adopt tobacco product standards, including with respect to cigarette ingredients, under Section 907 if appropriate for the protection of public health.[12] The powers of FDA and the rigorous requirements of Section 904 encompass the FCLAA's listing requirement, and go far beyond it.

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[5] See 15 U.S.C. § 1335a (requiring manufacturers and importers of cigarettes to "annually provide the Secretary [of HHS] with a list of the ingredients added to tobacco").
[6] *Id.*
[7] 50 Fed. Reg. 49617 (1985) (delegating administration of the reporting requirement to the CDC).
[8] 21 U.S.C. § 387d.
[9] P.L. 111-31, 123 Stat. 1776 (June 22, 2009).
[10] 21 U.S.C. § 387d(a).
[11] *Id.* § 387d(b).
[12] *Id.* § 387g.

II. HHS SHOULD DELEGATE ADMINISTRATION OF THE FCLAA'S REPORTING REQUIREMENT TO FDA

HHS should resolve the duplicative nature of the current information collection regime by delegating administration of the FCLAA's reporting requirements to FDA. In doing so, HHS would recognize that compliance with Section 904 subsumes and surpasses the FCLAA's mandate. The information provided to HHS under Section 904 dwarfs the composite list of ingredients added to tobacco in cigarettes required by the FCLAA: the information is brand-and quantity-specific and can encompass large amounts of additional documentation upon request.[13] More importantly, compliance with Section 904 satisfies the FCLAA's mandate that tobacco product manufacturers provide the HHS with "a list of the ingredients" added to tobacco in their cigarettes.[14] Through the FDA, HHS receives accurate and detailed information regarding ingredients added to tobacco in cigarettes, rendering CDC's collection of less detailed, unquantified, and non-brand-specific information no longer necessary.

Allowing FDA to administer the FCLAA mandate would resolve the key issues discussed in the Notice, as the current information collection regime is not "necessary for the proper performance of the functions" of CDC or HHS. Allowing the FCLAA to be satisfied through Section 904 would substantially increase "the quality, utility, and clarity of the information to be collected[;]" and the consolidation of duplicative reporting requirements will "[m]inimize the burden of the collection of information" on both the HHS and manufacturers of tobacco products.[15] While not the subject of the Notice, a change in delegations would also resolve the duplicative reporting of the ingredients in smokeless tobacco products.[16]

III. THE NOTICE UNDERESTIMATES THE BURDENS IMPOSED BY CDC'S INFORMATION COLLECTION REQUEST

CDC opines that, in complying with its request for information, "[t]here are ***no costs*** to respondents other than their time."[17] The estimation of the time required? A mere 6.5 hours per response.[18] The estimations in the Notice are simply not accurate, and they do not reflect the complexities of the cigarette manufacturing industry. Complying with CDC's request requires the time and attention of many employees. The Company must design searches to collect the information from its specification systems, transform that information to the format required by CDC, prepare the reporting forms, verify the information, and conduct a final review by Company management prior to submission. The Company estimates that the burden exceeds 30 hours for each cigarette ingredient submission. As discussed in Part II, HHS can, and should, take proper action to alleviate the duplicative burden of reporting ingredients added to tobacco in the manufacture of cigarettes to two different agencies within HHS.

CONCLUSION

The current regime for the collection of cigarette ingredient information results in duplicative burdens both for the Federal Government and for manufacturers of tobacco products. The HHS should delegate administration of the FCLAA's mandate in order to resolve the

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[13] *Id.*
[14] *Compare* 15 U.S.C. § 1335a *with* 21 U.S.C. §387(a).
[15] 84 Fed. Reg. 2526
[16] *Compare* the Comprehensive Smokeless Tobacco Health Education Act of 1986 (P.L. 99-252, 15 U.S.C. 4401 *et seq.*), 15 U.S.C. § 4403 (requiring reporting of the contents in smokeless tobacco products) *with* 21 U.S.C. § 387d (same).
[17] 84 Fed. Reg. 2526 (emphasis added).
[18] *Id.*

duplicative burdens imposed under the current reporting regime. Such a delegation would comply with the plain language of the FCLAA and Section 904 of the TCA and would also effectuate two key purposes of the Paperwork Reduction Act of 1995: to "minimize the paperwork burden ... resulting from the collection of information by or for the Federal Government" and to "improve the quality and use of" that information.[19]

Respectfully,

Michael W. Ogden

[19] 44 U.S.C. § 3501(1), (4).