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VIA ELECTRONIC FILING

May 4, 2021

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION TO ENSURE ACCURATELY REPORTED AND CONSISTENT LEVELS OF ALUMINUM IN ALL VACCINES	**:**	**Docket No. _____**

CITIZEN PETITION

This petition for administrative action is submitted on behalf of Christopher Exley PhD ("**Petitioner**") pursuant to 21 C.F.R. § 10.30 and related and relevant provisions of law (including the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act) to request that the Commissioner of Food and Drugs (the "**Commissioner**") take the actions listed below to assure accurately reported and consistent levels of aluminum in Adacel, Boostrix, Engerix-B, Havrix, Infanrix, Infanrix hexa, Kinrix, Pediarix, Pedvax-HIB, Pentacel, Prevnar-13, Synflorix, and Vaqta (the "**Subject Vaccines**").

A. ACTION REQUESTED

1. The Food & Drug Administration ("**FDA**") forthwith publicly release documentation sufficient to establish that the aluminum content in each Subject Vaccine is consistent with amount provided in its labeling.[1]

[1] The term "labeling" as used herein shall include all documentation from the manufacturer and the FDA with regard to a given product, including its package insert, product label, patient information sheet, and approval documents, and any other documents that list its ingredients.

2. The FDA forthwith pause distribution of each Subject Vaccine until it has confirmed and publicly released documentation sufficient to establish that the aluminum content in each Subject Vaccine is consistent with the amount provided in its labeling.

B. STATEMENT OF GROUNDS

3. Petitioner, Dr. Exley, has authored over 200 published peer reviewed articles regarding aluminum, has been a Professor of Bioinorganic Chemistry at Keele University for the last 29 years, and has otherwise spent almost his entire 37-year career studying aluminum and its biological effects. His CV is appended hereto as Exhibit A.

4. Petitioner along with four other researchers have reviewed the aluminum content of multiple doses of each of thirteen childhood vaccines licensed and approved by the FDA. Based on their analysis, only three vaccines of the thirteen tested contained the amount of aluminum indicated on its labeling. Six vaccines (Pentacel, Havrix, Adacel, Pedvax, Prevnar 13, Vaqta) contained a statistically significant greater quantity while four vaccines (Infanrix, Kinrix, Pediarix, and Synflorix) contained a statistically significant lower quantity. A copy of this peer-reviewed study with these findings are appended hereto as Exhibit B and is available at https://www.sciencedirect.com/science/article/pii/S0946672X21000523

5. These deviations from each product's labeling render the product adulterated and misbranded and violates various federal statutes and regulations, and therefore requires immediate action from the FDA, including ceasing distribution of these vaccines until this issue has been corrected. *See, e.g.*, 21 U.S.C. § 351; 21 U.S.C. § 352; 21 C.F.R. § 56; 21 C.F.R. § 57. Doses with less than the approved amount of aluminum adjuvant will not have the same efficacy. Doses with more than the approved amount of aluminum adjuvant raise safety concerns.

6. The FDA must ensure that vaccines in current use and those that will be on the market in the future are accurately labeled. Vaccine recipients and their caregivers must be able to rely on the FDA-approved labeling for these products, especially considering that they are given to babies and children.

C. ENVIRONMENTAL IMPACT

7. The undersigned hereby states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

D. ECONOMIC IMPACT

8. Economic impact information will be submitted upon request of the commissioner.

E. CERTIFICATION

9. The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

10. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

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