

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

American Academy of Pediatrics, et al.,

Plaintiffs,

v.

Food and Drug Administration, et al.,

Defendants.

Case No. PWG-18-883

STATUS REPORT

In accordance with the Court's revised remedial order (ECF No. 202), Defendants respectfully report as follows:

1. **Covered Applications:** This report includes information about "Covered Applications" as defined in paragraph 7 of the Court's revised remedial order. The FDA has used the same method for determining which applications constitute Covered Applications as it did in its May 13, 2022 status report (ECF No. 205). Defendants conferred with Plaintiffs, who agreed that the set of applications covered by paragraph 7 of the revised remedial order is the same as in the May 13, 2022 status report.

2. **Overall Progress:** The FDA remains committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. The FDA met its prior estimate of taking action on 51% of Covered Applications by June 30, 2022. ECF No. 205 at 3. The other estimates in the FDA's May 13, 2022 status report remain the agency's best forecast based on current information.

3. In accordance with the revised remedial order, the FDA will file another status report by October 26, 2022, reporting any revisions to its estimates.

Dated: July 28, 2022

Of counsel:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Dep't of Health and Human Services

MARK RAZA
Chief Counsel
United States Food and Drug Administration

WENDY S. VICENTE
Acting Deputy Chief Counsel for Litigation

JONATHAN SILBERMAN
Associate Chief Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Garrett Coyle
GARRETT COYLE (Bar No. 809812)
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Phone: (202) 616-8016
Fax: (202) 616-8470
garrett.coyle@usdoj.gov

Counsel for Defendants