DELAWARE HEALTH
AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

OFFICE OF THE DIRECTOR

Delaware Division of Public Health
DECLARATION OF SHORTAGE
Diphtheria/Tetanus (DT)

NOW COMES, the Division of Public Health, by and through Karyl T. Rattay, MD, MS, Director, pursuant to 16 Del. C. § 510(b), who has determined that a shortage of mercury-free Diphtheria/Tetanus (DT) vaccine exists for children under 8 years or pregnant women, and who sets forth this Declaration, and herein states as follows:

RECITALS

WHEREAS, pursuant to 16 Del. C. § 122 (1) the Department of Health and Social Services has "supervision of all matters relating to the preservation of the life and health of the people of the State;" and

WHEREAS, 16 Del. C. § 510 (a) restricts the administration of vaccines containing mercury to children under 8 years or pregnant women; and

WHEREAS, 16 Del. C. § 510 (b) (3) states that the prohibition against the use of vaccines containing mercury shall not apply when "the Director of the Division of Public Health or their designee determines that a shortage of the vaccine exists which could threaten the health of groups of individuals within the State including children under eight (8) years of age or pregnant women, and additional mercury-free vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions or by any other means."

WHEREFORE, the Director of the Division of Public Health determines that:

(1) There exists a shortage of supply of mercury-free Diphtheria/Tetanus (DT) vaccine that could threaten the health of children under the age of 8 and pregnant women in the State of Delaware.

(2) Additional mercury-free Diphtheria/Tetanus (DT) vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions, or by any other means; and

(3) The use of mercury containing Diphtheria/Tetanus (DT) vaccine is necessary to ensure these groups have access to vaccinations.

Revised: 6/9/2016

JESSE S. COOPER BUILDING • FEDERAL STREET • DOVER • DELAWARE
MAILING ADDRESS: 417 FEDERAL STREET • DOVER • DELAWARE • 19901
TELEPHONE: (302) 744-4700 • FAX: (302) 739-6659

IN SUPPORT of this determination, the Director finds as follows;

(1) The Diphtheria/Tetanus (DT) vaccine is administered to children less than 7 years of age whom the Pertussis vaccination is not recommended.

(2) The Diphtheria/Tetanus (DT) vaccine is indicated for active immunization of children up to age 7 years against diphtheria and tetanus.

(3) Sanofi-Pasteur is the sole manufacturer of the Diphtheria/Tetanus (DT) vaccine licensed for use in the USA and no formulation of the vaccine currently manufactured is mercury-free.

Pursuant to 16 Del. C. § 510, a provider administering a mercury containing vaccine pursuant to this determination of shortage shall inform the client, parent of legal guardian of the client that the vaccine contains mercury, that they believe the vaccine to be medically necessary, and that the Director of Public Health has made a formal determination that the vaccine may be administered due to the existence of the shortage of mercury-free vaccines.

This determination of shortage is applicable for 12 months from the date of signature, and may be re-issued or amended upon further determination by the Director. This determination will be rescinded prior to 12 months from the date of signature if the Director determines that an FDA-approved mercury-free vaccine is, or can be made, adequately available.

Karyl T. Rattay, MD, MS
Director

June 10, 2016
Date

Revised: 6/9/2016