MERCURY-FREE VACCINE ACT
EXEMPTION DECLARATION

NOW COMES, the Department of Public Health (hereinafter, the "Department"), by and through Eric E. Whitaker, Director, pursuant to the Mercury-Free Vaccine Act or Public Act 094-0614, sets forth this Exemption Declaration, and herein, states as follows:

RECITALS

WHEREAS, pursuant to 20 ILCS 2305/2, the Department "has general supervision of the interests of the health and lives of the people of the State" of Illinois; and

WHEREAS, pursuant to 410 ILCS 315/2, the Department has been charged with upholding "the public policy of this State that all children shall be protected, as soon after birth as medically indicated, by the appropriate vaccines and immunizing procedures to prevent communicable diseases which are or which may in the future become preventable by immunization"; and

WHEREAS, the State of Illinois has recognized and acknowledged through the Communicable Disease Prevention Act, 410 ILCS 315/1, that the general usage of "effective, safe and widely used vaccines and immunization procedures have been developed and are available to prevent …diseases and to limit their spread"; and

WHEREAS, historically in Illinois, local health departments and private providers have provided immunization services to adults, children and other high risk individuals since the mid-1970's. The vaccines are purchased by the individual providers or local health departments with local funds; and

WHEREAS, Public Act 93-0384 requires vaccination of residents in long term care facilities statewide annually with influenza and pneumococcal vaccines. The vaccines or immunization services for these individuals are provided by the private providers that sign the medical standing orders; and

WHEREAS, the Mercury-Free Vaccine Act, or Public Act 094-0614, has set forth that any mercury-containing vaccines that contain more than 1.25 micrograms of mercury per dose are to be banned commencing on January 1, 2006. A list of U.S. licensed vaccines without Thimerasol Content is attached as Exhibit A; and

WHEREAS, the Mercury-Free Vaccine Act also provides in Section 10 that the Department "may exempt the use of a vaccine from this Act if the Department finds that…(an) actual shortage of supply of a vaccine at a reasonable cost that would prevent a person from receiving the needed vaccine…"

WHEREFORE, after conducting a review of vaccines containing thimerosal, the Department Hereby Declares an EXEMPTION to the Mercury-Free Vaccine Act for use of each of the following vaccines: "Influenza 2006/2007 Multi-dose Formula" and any influenza vaccine needed in the event of a pandemic.

IN SUPPORT of this Exemption to the vaccines, the Department states as follows:

In evaluating the basis for the Exemption for Influenza 2006/2007 Multi-dose Formula, the Department established that the influenza vaccine for the Vaccines for Children (VFC) program was procured from the Centers for Disease Control (CDC) through a federal contract directly from the manufacturer, or via a distributor/reseller. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers. For VFC Program needs, the Department submitted an order for 100% preservative-free product. On April 12, 2006, the Department was notified by the CDC that Illinois' allocation of influenza vaccine would not reflect Illinois' request for 100% preservative-free product. The CDC informed the Department that because the amount of preservative-free vaccine requested by federal grantees exceeded the amount of thimerasol preservative-free vaccine available under the federal contract, the CDC instituted an allocation formula to ensure equitable distribution to all grantees. According to the current allocation, the Illinois VFC program expects that approximately 75% of the influenza vaccine received will be preservative free. It is unknown what the final percentage will be until the manufacturing process and total yield is completed. CDC has informed the Department that no additional preservative-free doses are available for purchase through the federal vaccine contract. As a result of the reduced allocation, neither Illinois nor Chicago will have sufficient vaccine supply available to serve those at highest risk of diseases and complications without the use of thimerosal containing formulations.

In evaluating the basis for the Exemption for each of the vaccines, the Department established that the vaccine was procured either directly from the manufacturer, or via a distributor/reseller. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers.

Further in the event of a pandemic, antiviral drugs and other influenza formulas may need to be administered to offer protection against the pandemic influenza strain. During a pandemic, influenza vaccine supplies may be limited. In order to effectively respond to the pandemic influenza and offer the protection of a vaccine, the public and private providers may need to employ vaccines containing preservatives in order to immunize the maximum amount of Illinois citizens.

The Department's evaluation involving the influenza vaccine supply.
Based upon the information provided by vaccine supplier, sanofi pasteur, limited amounts of Influenza vaccine are available for use in Illinois and lesser quantities of preservative-free vaccine (thimerosal free) are available for use in Illinois. The Department concludes that inadequate amounts of influenza vaccine containing less than 1.25 micrograms of preservative exist to meet the needs of the people of the State of Illinois for the upcoming year. The multidose formulation is the primary presentation administered by public and private providers throughout Illinois and must be exempted from the Act.

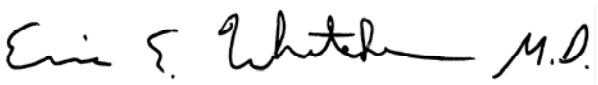
The vaccine dosage and thimerosal concentration are as follows:

Vaccine	Brand Name	Manufacturer	Thimerosal Concentration *
Influenza 2006/2007 Multi-dose Formula	Fluzone - multi-dose vial Fluvirin – multi-dose vial	sanofi pasteur Novartis(formerly Chiron)	0.01% 0.01%

* A concentration of 1:10,000 is equivalent to a 0.01% concentration. A 1:10,000 concentration contains 25 micorgrams of Hg per 0.5 mL.

The Department concludes an exemption for use of the above listed vaccines is needed due to findings of a shortage of supply at a reasonable cost. Such a shortage, without issuing an exemption could reasonably constitute an actual or potential public health emergency.

Accordingly, the Department, by and through its Director, pursuant to Section 10 of the Mercury-Free Vaccine Act, hereby exempts the use of the following vaccines: "Influenza 2006/2007 Multi-dose Formula and any influenza vaccine needed in the event of a pandemic" from the requirements of Public Act 094-0614. This Exemption is applicable until June 30, 2007 and may be reissued or amended upon further determination by the Department.



August 23, 2006

Eric E. Whitaker, M.D., M.P.H.
Director, Illinois Department of Public Health

Date

Exhibit A
U.S. Licensed Vaccines without Thimerosal Content

Vaccine	Brand Name	Manufacturer	Thimerosal Concentration
Anthrax	Biothrax	BioPort Corporation	0
DTaP	Infanrix	GlaxoSmithKline	0
DTaP	Daptacel	sanofi Pasteur	0
Tdap	ADACEL	sanofi Pasteur	0
Tdap	Boostrix	GlaxoSmithKline	0
Hib	ACTHIB	sanofi Pasteur	0
Hib	Hib TITER	Wyeth – Ayerst	0
Hib	Pedvax HIB liquid	Merck	0
Hib/Hep B	Comvax	Merck	0
Hepatitis A	Havrix	GlaxoSmithKline	0
Hepatitis A	Vaqta	Merck	0
Hepatitis B	Recombivax HB	Merck	0
HPV	Gardisil	Merck	0
IPV	IPOL	sanofi pasteur	0
Influenza	Fluzone-syringe and.5 ml vial	sanofi pasteur	0
Influenza	FluMist	MedImmune	0
Meningococcal	Menactra	sanofi pasteur	0
MMR	MMRII	Merck	0
MMR-Varicella	ProQuad	Merck	0
Pneumococcal	Prevnar	Wyeth-Ayerst	0
Pneumococcal	Pneumovax 23	Merck	0
Rabies	RabAvert	Chiron	0
Rabies	IMOVAX	sanofi pasteur	0
Rotovirus	RotaTeq	Merck	0
Typhoid Fever	Typhim Vi	sanofi pasteur	0
Typhoid Fever	Vivotif	Berna Biotech	0
Varicella	Varivax	Merck	0
Yellow Fever	YF-Vax	sanofi pasteur	0

Source: Institute for Vaccine Safety, Johns Hopkins University, June 21, 2006
www.vaccinesafety.edu