

Perspectives in
Pandemic
Influenza
Preparedness
FDA's Role in the
Development and
Licensure of
Seasonal &
Pandemic
Influenza vaccines

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Valency	Vaccine type	Trade name	Age range	Manufacturer
Trivalent	Inactivated, egg-based	Fluzone	≥ 6 months of age	Sanofi-Pasteur
		Fluzone High Dose	≥ 65 years of age	Sanofi-Pasteur
		Fluzone Intradermal	18 – 64 years of age	Sanofi-Pasteur
		Fluarix	≥ 3 years of age	GSK
		FluLaval	≥ 6 months of age	GSK
		Fluviron	≥ 4 years of age	Seqirus
		Agriflu	≥ 18 years of age	Seqirus
		Afluria	≥ 6 months of age	Seqirus Pty Ltd
	Inactivated, adjuvanted	Fluad	≥ 65 years of age	Seqirus
	Inactivated, cell-based	Flucelvax	≥ 4 years of age	Seqirus
	Recombinant Protein	Flublok	≥ 18 years of age	Protein Sciences Corp
	Live attenuated vaccine	FluMist	2 – 49 years of age	Astra Zeneca

Valency	Vaccine type	Trade name	Age range	Manufacturer
Quadrivalent (QIV)	Inactivated, egg-based	Fluzone QIV	≥ 6 months of age	Sanofi-Pasteur
		Fluzone Intradermal QIV	18 – 64 years of age	Sanofi-Pasteur
		FluLaval QIV	≥ 6 months of age	GSK
		Afluria QIV	≥ 6 months of age	Seqirus Pty Ltd
		Fluarix QIV	≥ 6 months of age	GSK
	Inactivated, cell-based	Flucelvax Quadrivalent	≥ 4 years of age	Seqirus Inc
	Recombinant Protein	Flublok Quadrivalent	≥ 18 years of age	Protein Sciences Corp
	Live attenuated	FluMist QIV	2 – 49 years of age	Astra Zeneca
Monovalent A/H5N1 (pandemic)	Inactivated, egg-based	n/a	18 – 64 years of age <ul style="list-style-type: none"> • 2 doses, 90 µg HA/dose 	Sanofi-Pasteur
	Inactivated, egg-based, adjuvanted	n/a	<ul style="list-style-type: none"> • ≥ 18 years of age, 3.75 µg HA with AS03 • 6 months -17 years of age, 1.9 ug HA with AS03_B 	GSK

U.S.-licensed Seasonal Influenza Vaccines: Routine Licensing Actions

- Each year, one or more of the vaccine strains may be replaced with a new strain
- FDA convenes VRBPAC to recommend influenza vaccine strains to be included in FDA-licensed vaccines based on WHO consultation on flu vaccine composition
- Submission of a prior approval manufacturing supplement to an existing biologics license application (BLA) is required for annual influenza strain change
 - “Strain change supplement”
 - Inactivated vaccines: No clinical data
 - Live attenuated: Limited clinical data
- Lot release

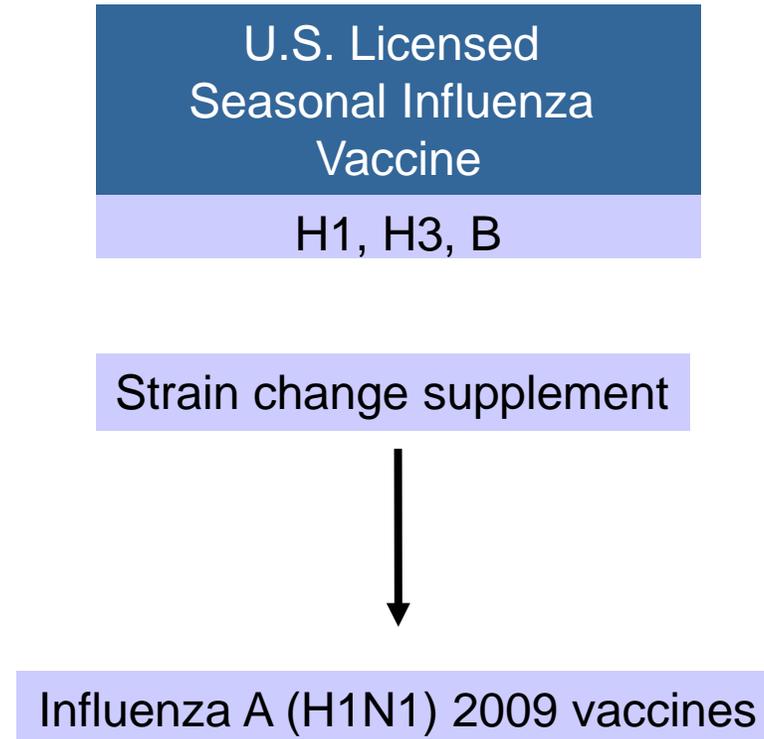
CBER is a WHO
Essential
Regulatory
Laboratory (ERL):
Influenza Product
Quality
Laboratories

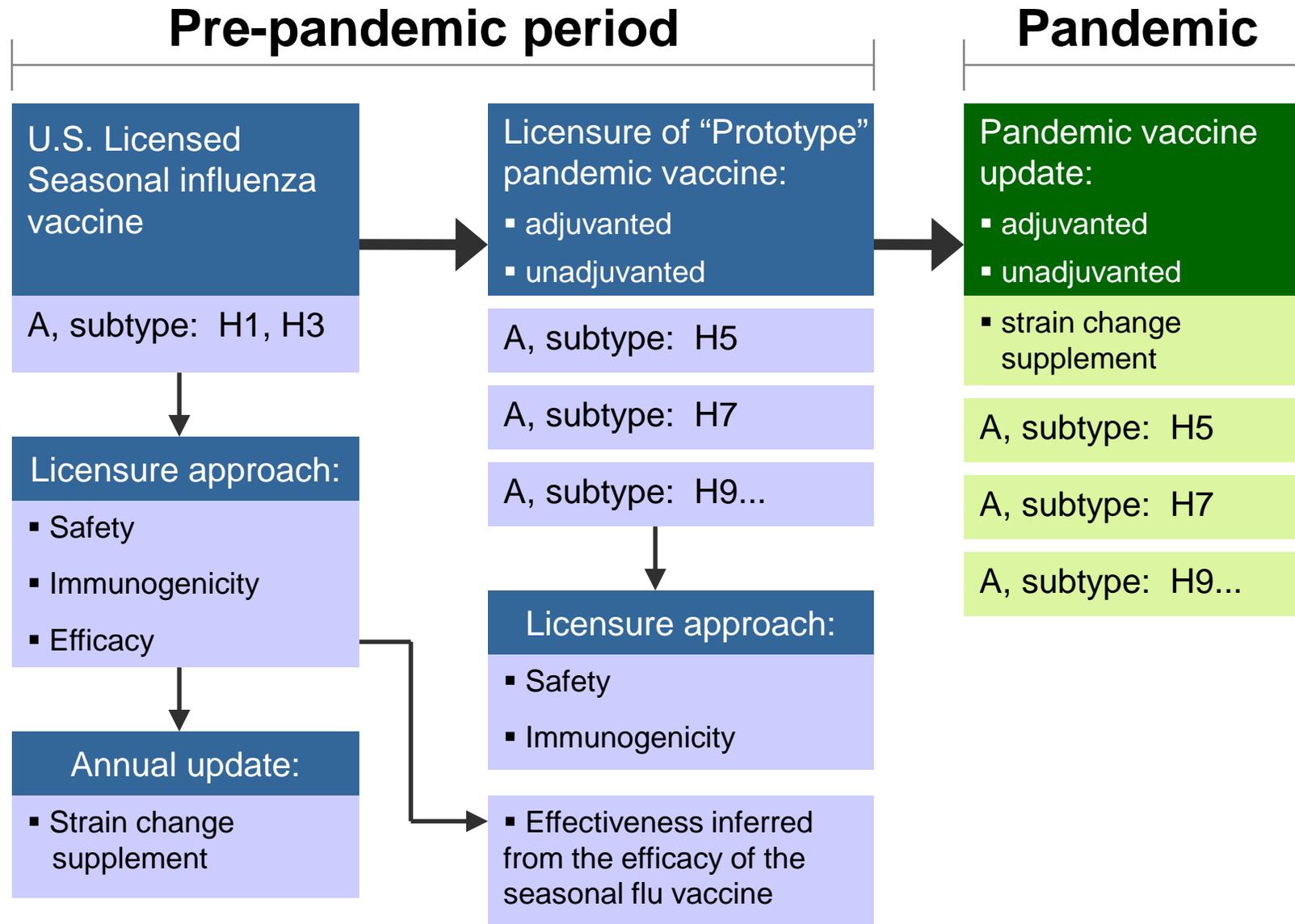
CBER's ERL activities include

- Yearly flu strain selection
- Antigenic characterization of circulating influenza isolates for strain selection purposes
- Generation of high growth reassortants viruses suitable for use in vaccine production
- Production, calibration and provision of SRID reference reagents to measure vaccine potency
- Antigenic confirmation of production seeds
- Lot release

US -Licensed Pandemic Influenza Vaccines: Influenza A (H1N1) 2009 Vaccines

- Approved as strain change supplements to the seasonal influenza virus vaccine BLAs
 - Consistent with licensure of seasonal vaccines
 - Consistent with past regulatory actions:
 - 1986 - Influenza A/Taiwan/1/86 H1N1
 - Monovalent vaccines licensed as strain change supplements
 - No clinical data
 - Supported by VRBPAC 7/2009





Pandemic
Influenza Vaccines
manufactured
using a process
that is not U.S.
licensed (with or
without adjuvant)

- Demonstration of effectiveness:
 - If the manufacturer develops a seasonal influenza vaccine:
 - Infer effectiveness of the vaccine from the efficacy of the seasonal made by the same process
 - If the manufacturer does not develop a seasonal vaccine
 - Accelerated Approval: Prelicensure safety and immunogenicity data required to support dose and dosing regimen
 - Manufacturer must verify clinical benefit during the pandemic

Guidance for Industry- Pandemic Influenza vaccines
2007

Preparing for the next Pandemic

Regulatory pathways to licensure are defined

Vaccine availability

- Continue to explore options to accelerate vaccine availability
 - Alternative manufacturing technologies/platforms
 - Cell-based, recombinant, adjuvants and delivery systems

Reagents/potency testing

- Development of alternatives to SRID are ongoing

Development of correlate of protection