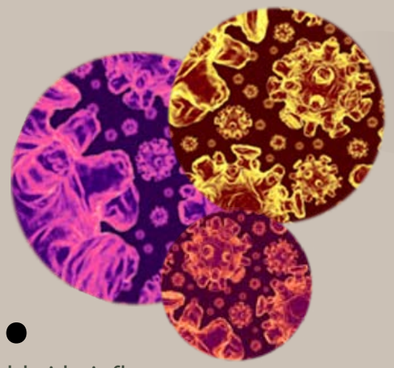
Yearly Steps to Influenza Vaccine Identification and Distribution



1. Worldwide influenza disease surveillance by the World Health Organization (WHO)

2. FDA and WHO review data to recommend the composition of influenza virus vaccines for next winter's influenza season.

3. Each February, FDA convenes its Vaccine and Related Biological Products Advisory Committee and recommends the three strains of influenza virus to include in the U.S. vaccine.

4. The viruses are adapted for use in manufacturing.

5. U.S. licensed vaccine manufacturers obtain reference influenza viruses from WHO Collaborating Centers to generate the "seed virus" for further vaccine manufacturing.

6. Using reagents developed and calibrated by FDA, manufacturers and the FDA test their vaccine for potency and safety.

7. Vaccine is formulated into standard dosages, and is filled and finished by the manufacturers into final containers such as vials, syringes, and sprayers.

8. Each vaccine set ("lot") must meet FDA's rigorous standards for safety and efficacy as it rolls off the manufacturer's production line.

FDA

9. FDA releases lots and the manufacturers begin shipping vaccine throughout the U.S. for use by the public.