The U.S. Food and Drug Administration (FDA) approved Fluad, the first seasonal influenza vaccine containing an adjuvant. According to their press release, Fluad was approved using the accelerated approval regulatory pathway, which allows the FDA to approve products for serious or life-threatening diseases based on evidence that the product has an effect on an outcome that is reasonably likely to predict clinical benefit. Under the accelerated approval requirements, a confirmatory study is required to verify and describe the clinical benefit of Fluad.

The biggest issue with the use of adjuvants for human vaccines, particularly routine childhood vaccines, is the toxicity and adverse side-effects of most of the adjuvant formulations. At present the choice of adjuvants for human vaccination reflects a compromise between a requirement for adjuvanticity and an acceptable low level of side-effects.

Other problems with the development of adjuvants include restricted adjuvanticity of certain formulations to a few antigens, use of aluminum adjuvants as reference adjuvant preparations under suboptimal conditions, non-availability of reliable animal models, use of non-standard assays and biological differences between animal models and humans leading to the failure of promising formulations to show adjuvanticity in clinical trials. The most common adjuvants for human use today are still aluminum hydroxide and aluminum phosphate, although calcium phosphate and oil emulsions also have some use in human vaccinations.

For more information visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm474295.htm and www.ncbi.nlm.nih.gov/pubmed/8585280