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GlaxoSmithKline

Management Dockets, N/A
Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1-23
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**Re: NAS 0; Not Product Specific
General Correspondence: Comments on Draft Guidance for Industry:
Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines
[Docket No. 2006D-0088]**

Dear Sir or Madame:

Reference is made to the notice published by FDA in the Federal Register on March 10, 2006 to invite written comments on a new draft guidance for industry, "Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines." The purpose of this submission is to provide comments from GlaxoSmithKline on this draft guidance.

GSK is a research-based pharmaceutical and biotechnology company. Our company is dedicated to the discovery, development, manufacture and distribution of medicines and vaccines that enable people to lead longer, happier, healthier and more productive lives. We appreciate the opportunity to comment on this draft guidance and recognize the public health importance of creating a regulatory framework for the development and registration of vaccines that can be available in the instance of an influenza pandemic.

In general we think the guidance is well-written and clearly describes the expectations of the Agency for the clinical data to support licensure of vaccines for pandemic influenza. We have the following specific comments:

- 1. The draft guidance does not provide a recommendation on the type of strains of influenza to be assessed for pandemic vaccines.**

We recommend that the final guidance reflects that the clinical data to be generated should be with a noncirculating strain of influenza to mimic the situation of a pandemic.

2. Sections III. B, Approval of a Pandemic Influenza Vaccine as a Supplement to a U.S. Licensed Trivalent Live Attenuated Influenza Vaccine and III. C, Accelerated Approval of a BLA for a Pandemic Influenza Vaccine

In the draft guidance, effectiveness data are listed as criteria for licensure of a pandemic vaccine when following accelerated approval; however, no effectiveness data are listed for licensure of a pandemic vaccine when filing as a supplement to an existing BLA. There is a major difference between the seasonal trivalent vaccine and the pandemic vaccine in the pre-immune status of the population: the population is immunologically naive to the pandemic strain. Therefore, even if the pandemic vaccine is a sBLA submission (i.e. same process, no other excipients/adjuvant than seasonal trivalent vaccine), the requirements in terms of effectiveness should be the same for both licensing routes, sBLA and new BLA. We are not certain why effectiveness/immunogenicity data in a "primed" population would be supportive for the pandemic situation.

3. Section III.C.1.b, describing the possible approach of a noninferiority comparison to the U.S. licensed pandemic influenza vaccine for establishing effectiveness based on immune responses under an accelerated approval

The draft guidance states sponsors should use doses of a U.S. licensed pandemic influenza vaccine for this non-inferiority comparison. It is our understanding that all doses would be in government-owned stockpiles, and not available through the usual distribution channels. Please clarify this situation in the final guidance document.

Again, we thank you for the opportunity to provide comments. This submission is provided in electronic format according to the instructions provided at <http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cgm?AGENCY=FDA>.

Please contact me at (919) 483-6405 or my colleague Ozzie Berger at (610) 787-3770, if you require clarification or have any questions about these comments. Thank you.

Sincerely,



Anne N. Stokley, M.S.P.H.
Director, Policy, Intelligence & Education
US Regulatory Affairs