APOTEX
ADVANCING GENERICS

April 6, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0129
Apotex Inc.'s response to FDA's request for public comment on the information requirements for Biosimliars Interchangeability Federal notice.

Dear Sir or Madam,

Apotex Inc. is an independent, dynamic, Canadian pharmaceutical company committed to R&D, manufacturing and distributing a broad range of high-quality, affordable medicines to patients, healthcare providers, payers and governments worldwide.

Apotex acknowledges the efforts of the agency on the notice in the Federal Register soliciting public comments on the information collection for a proposed bio similar product and an application for a supplement for a proposed interchangeable product. We appreciate the opportunity to comment on this notice and would like to provide recommendations for your consideration in a separate attachment. We look forward to a continued collaboration with the FDA.

Apotex Corp. appreciates FDA's willingness to accept input from industry and other stakeholders. Please direct any questions or requests for any additional information to me at Apotex Corp., the authorized US agent for Apotex Inc., by telephone at (954) 384-3986 or fax (866) 392-1774 or email at kkrishna1@apotex.com

Sincerely,

Kiran Krishnan
Vice President, US Regulatory Affairs

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Notice Specific Comments:

Quote from Federal Register	Comment from Apotex
Page 2: **#1** **"The information submitted to meet the standard for interchangeability must show that:** **(1) The biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient** **(2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."**	Apotex requests the agency to provide clarity and interpretation for the following requirements; Although it is stated in Quote #1) that information should be provided (not necessarily clinical data) , Quote #2 implies that switching studies may be required to provide proof of safety of the biosimilar product to the reference product. Apotex requests FDA to provide additional clarification on the scope of information required to demonstrate the proof of safety of a biosimilar product.
Page 2: **#2:** **"To demonstrate interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and that the biosimilar biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biosimilar biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch"**	

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Quote from Federal Register	Comment from Apotex
Page 2: **"FDA may determine, in its discretion, an element required under a 351(k) application to be unnecessary to support licensure of a biosimilar or interchangeable product."**	Apotex requests the Agency to clarify the timelines and the chosen mode of communication for the FDA to convey to the stakeholders any details on an unnecessary element under a 351(k) application, Apotex is of the opinion that if such information is provided to the stakeholders from time to time in the form of a guidance or a notice, it will prevent them from exhausting resources to collect data that is unnecessary for review of a 351(k) application.

Quote from Federal Register	Comment from Apotex
Page 2: **"The information submitted to meet the standard for interchangeability must show that:** **(1) The biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient** **(2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."**	Apotex requests the Agency to provide clarification on how the consistency of the clinical results for any given patient is demonstrated for the reference product. Additionally, Apotex also requests the Agency to elucidate how the risks in terms of safety or diminishing efficiency for the reference product are established for an individual patient.

Quote from Federal Register	Comment from Apotex
Page 2: **"In order to demonstrate interchangeability, the fact that an applicant must provide sufficient information to demonstrate biosimilarity"**	Apotex requests the Agency to elaborate the quote from the federal register to detail the extent of demonstrated biosimilarity which would be considered for interchangeability.