Comparative Table of Data Exclusivity Provisions in U.S. Free Trade Agreements and the U.S. Proposal to the Trans-Pacific Partnership (TPP) Agreement

Item	U.S. TPP Proposal	U.S.-Singapore FTA (2004)	U.S.-Chile FTA (2004)	U.S.-Australia FTA (2005)	U.S.-Peru FTA (2006)
Protection applies to a	product, the origination of which involves a considerable effort	product	product which utilizes a new chemical entity	product	product that utilizes a new chemical entity
Protection covers the	information concerning the safety and efficacy	information concerning the safety and efficacy	undisclosed information concerning the safety and efficacy	undisclosed test or other data concerning safety or efficacy	undisclosed test data or other data necessary to determine whether the use of such products is safe and effective
Obligation of the Regulatory Authority	not authorize a third person to market	not permit third parties to market	not permit third parties to market	not permit third persons to market	protect against disclosure of the data provide that no other person rely on such data in support of an application
The protection extends to	same or a similar product	same or a similar product on the basis of the approval	such product	same or similar product on the basis of that information	product
Duration of protection	at least five years	at least five years	at least five years	at least five years	a reasonable period shall normally mean five years
Scope of protection	*no exceptions specified*	*no exceptions specified*	protect such information against disclosure except where necessary to protect the public	*no exceptions specified*	protect against disclosure of data, except where the disclosure is necessary to protect the public.
Products previously approved in the other territory	not authorize a third person to market same or similar product for at least five years	defer the date of any such approval to third parties for at least five years	*no provision*	not permit third persons to market the same or similar product for at least five years	If a party grants approval within six month from the filing of application, the reasonable period shall begin with the date of the first marketing approval relied on.
Protection of new clinical information	new clinical information that is essential to the approval of the pharmaceutical product at least for 3 years	*no provision*	*no provision*	new clinical information that is essential to the approval of the pharmaceutical product at least for 3 years	data exclusivity provisions do not apply
Safeguards	*No safeguards specified*	*No safeguards specified*	*No safeguards specified*	*No safeguards specified*	may take measures to protect public health in accordance with the TRIPS Agreement and the Doha Declaration

*Please note that there is no provision in the TRIPs Agreement on data exclusivity. Article 39.3 provides for protecting undisclosed test data against unfair commercial use: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use”.