FDA: Draft Bill to Eliminate Preannouncements for Foreign Drug Inspections

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In a recent Sidley Life Sciences Update, we informed our clients that, in January 2022, a Creating Efficiency in Foreign Inspections Act was introduced to the U.S. Senate. The draft law proposes to eliminate the Food and Drug Administration (FDA) practice of preannouncing foreign surveillance inspections. In this briefing, we look at the possible consequences for Swiss pharmaceutical companies if the bill should pass.

FDA's Current Practice

Historically, the FDA has notified drug manufacturers located outside of the United States weeks or months in advance of a planned surveillance inspection, whereas FDA typically provides no notice to domestic drug manufacturers. FDA generally preannounces foreign inspections because its inspectional authority under Section 704 of the Federal Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. § 374) does not apply outside the United States. Rather, FDA's foreign inspections are conducted voluntarily with the understanding that, should a facility refuse FDA's inspection, then a product manufactured at the site will not be allowed to be imported into the United States, and/or FDA will not approve pending drug applications listing the facility. Accordingly, preannouncement documents the foreign firm's agreement to allow FDA inspection and ensures the foreign facility is operating on the dates FDA plans to inspect.

Recently, the Senate Committee on Finance suggested that the delay between notice and inspection gives some foreign drug facilities sufficient time to conceal noncompliance at their facilities.

The New Draft Bill

On January 13, 2022, two Republican Senators introduced the Creating Efficiency in Foreign Inspections Act. Under this bill, the FDA would no longer provide advance notice of foreign drug inspections.

The new bill proposes to amend Section 704 of the FDCA to allow FDA to inspect foreign drug manufacturers without advance notification unless notice is mandated by the host country or is required to protect public health. Notably, the requirements of the bill apply only to surveillance inspections and not to preapproval, prelicensure, or for-cause inspections.

Consequences for Swiss-Based Pharmaceutical Companies

According to Article 64a of the Swiss Federal Act on Therapeutic Products (TPA), competent foreign authorities shall be entitled to inspect Swiss establishments operating in the therapeutic products sector under certain circumstances, provided the Swiss Agency for Therapeutic Products (Swissmedic) is notified of such an inspection beforehand.

According to its wording, Article 64a of the TPA at first glance provides a basis only for the notification and involvement of Swissmedic but not of the company whose site(s) in Switzerland are to be inspected by the foreign authority.

However, Article 64a para. 1 let. c of the TPA requires consent by the establishment concerned. This, again, implies that the inspection has to be not only preannounced but also accepted by the affected company.

Therefore, Section 704(i)(1)(A) of the FDCA would apply by virtue of Article 64a of the TPA, meaning that Swiss sites will not have to face unannounced inspections even if the new bill should pass the U.S. Congress. Thus, the newly introduced bill will presumably not change anything for Swiss sites to be inspected by FDA.