FDA REGULATORY REPORT

Prepared for the Embassy of the Republic of Korea in the USA
October 23, 2020

KHIDI Korea Health Industry Development Institute

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This document is a report delivered pursuant to the terms of an engagement letter between Reed Smith LLP and the Embassy of the Republic of Korea ("Embassy") . We prepared this report to provide a comprehensive and updated understanding of FDA's policy and legal and regulatory requirements pertaining to medical products intended for use against COVID-19 during the current public health crisis.

Please note that FDA's policy and legal and regulatory requirements are subject to frequent modifications during the current crisis. The content of this report is only accurate as of October 23, 2020. Please let us know if you have any questions or comment regarding any content included in this report.

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THE U.S. FOOD AND DRUG ADMINISTRATION STATUTORY AND REGULATORY REGIME FOR THE DEVELOPMENT OF DRUGS, BIOLOGICS, AND MEDICAL DEVICES

I. PRE-MARKET AUTHORITY UNDER THE FDCA

In the United States, the Food and Drug Administration (" FDA ") regulates drugs, biologics, and medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") [1] , the Public Health Services Act (the " PHSA "), and their implementing regulations. The ambit of FDA's authority is defined almost exclusively by the list of medical product categories (e.g., drugs, biologics, and medical devices) for which it has jurisdiction. As a result, how medical products are classified shapes the regulatory requirements and processes that apply to any given medical product. The main categories for which FDA possesses regulatory authority are: (1) drugs, (2) biologics, and (3) medical devices. The FDCA also grants FDA authority to regulate food and cosmetics, among others.

A. Classification of Drugs and Biologics and Marketing Authorization Pathways

Under the FDCA, drugs are defined as:

> articles recognized by an official pharmacopoeia or formulary;
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> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease;
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> articles (other than food) intended to affect the structure or any function of the body; and
>
> articles intended for use as a component of any articles specified above, but not a device or a component, part, or accessory of a medical device. [2]

The broad definition of what constitutes a drug provides FDA with significant authority to regulate a wide universe of articles as drugs, generally subjecting such articles to FDA's stringent pre-market regulatory requirements and procedures.

Generally, a drug is considered a *new drug* if it is not generally recognized as safe ("GRAS") and effective by qualified scientific experts for the condition of use. [3] New drugs will typically require submission of a new drug application ("NDA") before receiving pre-market approval. There are, however, certain categories of drugs that are subject to different standards for pre-market authorization and approval.

Generic drugs are medications created to have the same dosage, safety, strength, quality, route of administration, performance, and intended use of an already approved brand-name drug. [4] The FDA Generic Drugs Program requires rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. Part and parcel of this process is the requirement that manufacturers of generic drugs submit an abbreviated new

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[1] 21 U.S.C. § § 301 – 392.

[2] *Id.* § 201(g).

[3] *Id.* § 201(p)(1).

[4] FDA, *Generic Drug Facts* (June 1, 2018), accessible at https://www.fda.gov/drugs/generic-drugs/generic-drug-facts#:~:text=A%20generic%20drug%20is%20a,same%20as%20brand%2Dname%20medicines .

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- 제품 분야 Area of industry(ex; medical device, phamaceutical…. Etc)
- 신청자 성명 Full name
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