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山東新華製藥股份有限公司

Shandong Xinhua Pharmaceutical Company Limited

(a joint stock company established in the People's Republic of China with limited liability)

(Stock Code: 00719)

OVERSEAS REGULATORY ANNOUNCEMENT

This overseas regulatory announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Shandong Xinhua Pharmaceutical Company Limited (the “**Company**”) will publish the “Announcement on Icosapent Ethyl Having Obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs” on CNINFO <http://www.cninfo.com.cn> (巨潮資訊網) on 20 May 2025. The English translation of the relevant document is hereby included for reference. If there is any inconsistency between the English version and the Chinese version, the Chinese version shall prevail.

By Order of the Board

Shandong Xinhua Pharmaceutical Company Limited

He Tongqing

Chairman

19 May 2025, Zibo, PRC

As at the date of this announcement, the Board comprises:

Executive Directors:

Mr. He Tongqing (*Chairman*)
Mr. Xu Wenhui
Mr. Hou Ning

Non-executive Directors:

Mr. Xu Lie
Mr. Zhang Chengyong

Independent Non-executive Directors:

Mr. Pan Guangcheng
Mr. Zhu Jianwei
Mr. Ling Peixue
Ms. Cheung Ching Ching, Daisy

Shandong Xinhua Pharmaceutical Company Limited**Announcement on Icosapent Ethyl Having Obtained the Notification of Approval of Marketing Application for Chemical Substance Drugs**

The Company and its board of directors confirm that the contents of this announcement are true, accurate and complete without any false information, misleading statements or material omissions.

Shandong Xinhua Pharmaceutical Company Limited (hereinafter referred to as “**Xinhua Pharmaceutical**” or the “**Company**”) has recently received the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书) (hereinafter referred to as the “**Product**”) issued under the authority of the National Medical Products Administration (“**NMPA**”) in connection with its Icosapent Ethyl. Relevant information is now announced as follows:

I. Basic information

Drug name:	Icosapent Ethyl
Dosage form:	Active Pharmaceutical Ingredients
Registration classification:	Chemical drugs
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Application for the Listing of Domestic Production of Chemical Raw Materials
Reception number:	CYHS2360419
Registration number:	Y20230000457
Notification number:	2025YS00375
Review conclusion:	According to the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and applicable regulation, upon review, the Product conforms to applicable requirements for drug registration and is approved for registration. The standard of quality, labelling as well as the production processes concerning the Product shall be consummated in accordance with relevant documentation.

II. Other relevant information

In June 2023, Xinhua Pharmaceutical submitted an application to the Center for Drug Evaluation of the National Medical Products Administration for the registration of Icosapent Ethyl(i.e. the Product) and such application was accepted. In May 2025, Xinhua Pharmaceutical obtained the *Notification of Approval of Marketing Application for Chemical Substance Drugs* (化学原料药上市申请批准通知书), and the review conclusion was to approve the registration of the Product.

The Product is used to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia ($\geq 500\text{mg/dL}$) on the basis of dietary control. It is used in combination with statins for the treatment of adults with established cardiovascular disease or diabetes or other ≥ 2 cardiovascular disease risk factors, as well as

with hypertriglyceridemia (≥ 150 mg/dL) to reduce the risk of cardiovascular incidents.

The Product can be used for both medicinal and health care purposes. According to relevant statistics, the global sales of Icosapent Ethylin 2023 amount to approximately 1.838 billion United States dollars.

III. Impact on the Company and risk warning

The receipt by Xinhua Pharmaceutical of the *Notification of Approval of Marketing Application for Chemical Substance Drugs* in connection with its Icosapent Ethylin in May 2025 will further enrich the Company's product line and enhance its comprehensive competitiveness.

The pharmaceutical sales business is susceptible to changes in domestic pharmaceutical industry policies, bidding and procurement processes, changes in the market environment and other factors, and is subject to uncertainty. Investors are advised to invest sensibly and pay attention to investment risks.

By Order of the Board
**Shandong Xinhua Pharmaceutical Company
Limited**

19 May 2025