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 Soft Capsules Having Obtained Drug Registration Certificate" on CNINFO http://www.cninfo.com.cn (巨潮資訊網) on 6 June 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

5 June 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 Soft Capsules Having Obtained Drug Registration Certificate

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 Drug Registration Certificate（药品注册证书）for its Icosapent Ethyl soft capsules (hereinafter referred to as the "**Product**") approved and issued by the National Medical Products Administration. Relevant information is now announced as follows:

I. Basic information

Drug name:	Icosapent Ethyl Soft Capsules
Dosage form:	Capsule
Specifications:	1.0g; 0.5g
Drug category:	Prescription drugs
Registered classification:	Class 4 chemicals
Applicant:	Shandong Xinhua Pharmaceutical Company Limited
Application matter:	Drug registration (Domestic production)
Case number:	CYHS2303096; CYHS2303097
Drug approval number:	National Medicine Zhunzi (国药准字)H20254286;National Medicine Zhunzi (国药准字) H20254287
Notification number:	2025S01513;2025S01514
Review conclusion:	In accordance with the Pharmaceutical Administration Law of the People's Republic of China (中华人民共和国药品管理法) and relevant regulation, upon review, the Product conforms with the applicable requirements of drug registration, and the drug registration certificate has been issued. The standard of quality, product instructions, labels as well as production process concerning the Product shall be consummated in accordance with relevant documentation. Pharmaceutical production enterprises are required to meet requirements of pharmaceutical production quality management standards prior to the production and sale of drugs.

II. Other relevant information

In November 2023, Xinhua Pharmaceutical submitted application materials to the Center for Drug Evaluation of the State Drug Administration (药品审评中心) (CDE) concerning the marketing of Icosapent Ethyl soft

capsules and the application materials were accepted. In June 2025, Xinhua Pharmaceutical obtained the Drug Registration Certificate, and the review conclusion was that the Product shall be approved for registration.

The Product is used to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia (≥ 500mg/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 combined with hypertriglyceridemia (≥ 150 mg/dL) to reduce the risk of cardiovascular incidents.

According to relevant statistics, the global sales of Icosapent Ethyl in 2023 amount to approximately 1.838 billion United States dollars.

III. Impact on the Company and risk warning

The obtaining of approval by the Product will help enhance the overall competitiveness of the Company in the field of cardiovascular disease treatment.

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

5 June 2025