

客户通知

变更控制: CC842

日期: 2019年1月25日

尊敬的客户:

本通知的发布意在根据我们的客户通知要求, 提供有关胎牛血清产品 (FBS) 的变更信息。

变更内容:

- 产地为澳大利亚, 且符合中国进口条件的胎牛血清 SKU 的微小变更

变更目的:

提高产品的完整性、差异化以及可追溯性, 并确保符合出口要求。

对 SKU 进行微小的变更, 旨在确保我们能够分离和识别出符合以及不符合中国进口条件的产品, 以确保将符合中国监管要求的血液制品出口到中国。我们将在所有供往中国的澳大利亚来源的 FBS 的现有 SKU 末尾添加后缀“C”来实现这一目的。

变更详细说明:

产地为澳大利亚且符合中国进口条件的胎牛血清的产品货号末尾将增加后缀“C”, 以识别和区分符合与不符合中国进口条件的产品。请参见下表查看所涉及到此变更的 SKU:

现行的 SKU 号	变更后的新 SKU 号
A3161001	A3161001C
A3161002	A3161002C
10099133	10099133C
10100139	10100139C
10099141	10099141C
10100147	10100147C
12664025	12664025C
10101145	10101145C

SKU 变更将从 2018 年 11 月 27 日起生产的所有产品开始生效。

对成品的影响:

所有成品仍将遵循变更前所确立的相同规范。这些成品将继续沿用我们产品的高质量标准，仍将适用于您的生物制品的生产。与没有后缀“C”的现行的 AUS FBS 相比，有后缀“C”的货号 FBS 的产品质量、稳定性及性能均不会受到影响，并且其生产、测试标准、储存以及运输方法或过程也均不会发生改变。

变更的客户批准:

此通知无需客户批准，更改将按上述规定实施。

如果您还有任何其他问题，烦请告知。

此致

敬礼！



Parminder Kaur
质量系统经理
澳大利亚

Parminder.kaur@thermofisher.com

Customer Notification

Change Control: CC842

Date: 25 January 2019

Dear Valued Customer,

This notification is to provide information regarding a change to the Fetal Bovine Serum product (FBS), as per our customer notification requirements.

Description of Change:

- Minor change to the SKUs for Australian Origin China Eligible Fetal Bovine Serum

Purpose of Change:

To enhance product integrity, differentiation and traceability and assuring compliance to export requirements.

The minor change to the SKU is to ensure that we can segregate and identify China eligible products from non-China Eligible products to ensure compliance to requirements for exporting blood products into China. This will be achieved by adding a "C" suffix to all existing SKU's of Australian origin FBS supplied to the China market.

Detailed Description of Change:

The product labels for Australian Origin China Eligible Fetal Bovine Serum will now have suffix "C" to identify and differentiate product as China Eligible from non-China eligible. Please refer to table below for SKUs impacted:

Current SKU Number	New SKU Number
A3161001	A3161001C
A3161002	A3161002C
10099133	10099133C
10100139	10100139C
10099141	10099141C
10100147	10100147C
12664025	12664025C
10101145	10101145C

The SKU change will come into effect for all product manufactured from November 27, 2018 onwards.

Finished Products Impacted:

All finished products will continue to meet the same specifications established prior to the changes. These finished products will continue to represent our high quality standard for product which is suitable for the production of your biological products. In comparison to our AUS FBS

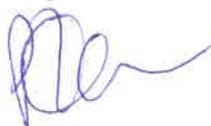
SKUs without C product quality, stability or performance will not be impacted and there will be no changes in the manufacturing, testing standards, storage or transport processes.

Customer Approval of Change:

Please note that **NO** Customer approval is required for this notification and the change will be implemented as stated.

Please advise if you have any further questions.

Best regards,

A handwritten signature in blue ink, appearing to be 'PK' followed by a flourish.

Parminder Kaur
Quality Systems Manager
Australasia

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