

Supplementary Information Certificate of a Pharmaceutical Product for CDER Products

Form FDA 3713f

(Currently approved under OMB Control Number 0910-0498)

CHANGE REQUEST (83-C)

Date: June 18, 2015

The NOA Posted on 6/15/15 was incorrect. The form name in the chart should be “Supplementary Information Certificate of a Pharmaceutical Product for CDER Products” and not what was listed “Supplementary Information Certificate to Foreign Government Requests.” CDER only issues one export certificate type, Certificate of a Pharmaceutical Product.

The OMB NOA dated 6/15/2015 should be changed as follows:

List of ICs			
IC Title	Form No.	Form Name	CFR Citation
CBER Export Certificate (FDA 3613, 3613b, 3613c)	FDA 3613c, FDA 3613, FDA 3613a, FDA 3613b	Supplementary Information Non-Clinical Research Use Only Certificate, Supplementary Information Certificate to Foreign Government Requests, Supplementary Information Certificate of Exportability Requests, Supplementary Information Certificate of a Pharmaceutical Product	
CDRH Export Certificate (FDA 3613, 3613a, 3613c)	FDA 3613c, FDA 3613a, FDA 3613	Supplementary Information Non-Clinical Research Use Only Certificate, Supplementary Information Certificate of Exportability Requests, Supplementary Information Certificate to Foreign Government Requests	
CVM Export Certificate (FDA 3613, 3613b)	FDA 3613a, FDA 3613, FDA 3613b	Supplementary Information Certificate of Exportability Requests, Supplementary Information Certificate to Foreign Government Requests, Supplementary Information Certificate of a Pharmaceutical Product	

CDER Export Certificate (FDA 3613f)	Form FDA 3613f	Supplementary Information Certificate of a Pharmaceutical Product for CDER Products	
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