

GDUFA Backlog Arrears List (As of 8/05/2019*)

The following applicants have one or more Abbreviated New Drug Applications (ANDAs) that have not satisfied the backlog fee required under GDUFA. The one-time backlog fee, incurred pursuant to § 744B(a)(1), was due no later than November 26, 2012. Failure to timely submit payment of the backlog fee means that the Food and Drug Administration (FDA) will not be able to receive new ANDAs or PASs within the meaning of § 505(j)(5)(A) submitted by the owner or affiliates on or after October 1, 2012 until the outstanding fee is paid. See § 744B(g)(1). In order to remedy this statutory penalty and permit FDA to proceed with consideration of the ANDA, please submit the one-time backlog fee(s) as soon as possible.

If your records indicate that the backlog fee has previously been submitted or you have questions, please contact AskGDUFA@fda.hhs.gov and provide the following information: ANDA Number, User Fee Payment I.D. Number (PIN), the payment method, date, and amount.

CHEMIBIOTIC IRELAND LTD
SCOLR PHARMA INC
SUZHOU HOMESUN WANQING PHARMACEUTICAL CO LTD

* This list will be updated only when changes occur to the applicants included in the list.