

## **GDUFA Backlog Arrears List (12/7/12)**

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](mailto:AskGDUFA@fda.hhs.gov) and provide the following information: ANDA Number, User Fee Payment I.D. Number (PIN), and the payment method, date and amount.

ACELLA PHARMACEUTICALS LLC  
ADCOCK INGRAM LTD  
ALAMO PHARMA SERVICES INC  
ALAUNUS PHARMACEUTICAL LLC  
ALCON RESEARCH LTD  
ALKALOIDA CHEMICAL CO ZRT  
ALTA PHARMA LLC  
ALTAIRE PHARMACEUTICALS INC  
ALVOGEN INC  
ANTARES PHARMA INC  
ASPEN GLOBAL INC  
BD RX INC  
BICON PHARMACEUTICAL INC  
BRIGHAM AND WOMENS HOSP  
CALL INC DBA ROCHESTER PHARMACEUTICALS  
CHEMIBIOTIC IRELAND LTD  
CLARIS LIFESCIENCES LTD  
COLGATE PALMOLIVE CO  
CORIUM INTERNATIONAL INC  
CYPRESS PHARMACEUTICAL INC  
DERMAPHARM CORP  
ECLIPSE PHARMACEUTICALS LLC  
EUTICALS SPA  
EXELA PHARMA SCIENCES LLC  
FDC LTD  
HAMPTON LAINE LLC  
HANSAMED INC  
HERITAGE PHARMACEUTICALS INC

IPCA LABORATORIES LTD  
IQA BIOPHARMA INC  
ISTITUTO BIOCHIMICO ITALIANO SPA  
IVAX PHARMACEUTICALS INC  
JUBILANT HOLLISTERSTIER LLC  
LEHIGH VALLEY TECHNOLOGIES INC  
LEO LABORATORIES LTD  
LINEPHARMA FRANCE  
LYCORED BIO LTD  
MICRO LABS LTD INDIA  
MIKAH PHARMA LLC  
MISSION PHARMACAL CO  
MUSTAFA NEVZAT IIAC SANAYII AS  
NORTHSTAR HEALTHCARE HOLDINGS  
NOVAST LABORATORIES LTD  
NOVOCOL INC  
ORCHID HEALTHCARE  
ORIENT PHARMA CO LTD  
PFIZER INC  
PHARMACARE LTD  
PHARMACOSMOS AS  
PROMED EXPORTS PVT LTD  
QILU TIANHE PHARMACEUTICAL CO LTD  
ROUSES POINT PHARMACEUTICALS LLC  
RUBICON RESEARCH PVT TLD  
SCOLR PHARMA INC  
SHARON BIO MEDICINE LTD  
SINTETICA SA  
SOLCO HEALTHCARE US LLC  
SPECTRA MEDICAL DEVICES INC  
STRIDES ARCOLAB LTD  
SUN PHARMA GLOBAL FZE  
SUN PHARMA GLOBAL INC  
SUZHOU HOMESUN WANQING PHARMACEUTICAL CO LTD  
SYNTHO PHARMACEUTICAL INC  
TABUK PHARMACEUTICAL MFG CO  
UMAN PHARMA INC  
UNITED BIOMEDICAL INC  
VISION PHARMA LLC  
VITARINE CO INC SUB WEST CHEMICAL PRODUCTS INC  
WOCKHARDT LTD  
WRASER PHARMACEUTICALS LLC  
YAOPHARMA CO LTD  
ZENOTECH LABORATORIES LTD  
ZHUHAI UNITED LABORATORIES CO LTD  
ZYDUS NOVELTECH INC