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in april 2014, after the company was contacted by the department of justice, the company voluntarily ceased and destroyed all unsold xibrom and paid a reported \$6.7 million fine to resolve fda allegations that the company provided illegal inducements to health care providers in return for promoting xibrom for the treatment of bipolar depression and/or other psychiatric conditions. the government's investigation has also revealed that from 2007 through 2012, ista, a relatively small pharmaceutical company, paid more than \$29.6 million in illegal remuneration to 3,050 health care providers and others in connection with its promotion of xibrom for the treatment of bipolar disorder, ista has acknowledged its responsibility and liability for this illegal conduct. today's guilty plea and the final, global settlement resolve all federal criminal liability arising from ista's illegal activity. also today, ista has entered into the divestiture agreement, which, with approval from cms, will result in the immediate sale to b+l and the immediate divestiture of all ista's remaining pharmaceutical and health care assets, including the drugs alofit and xibrom, to a new company that will be a limited partner of b+l. the new company will continue the development and marketing of xibrom for bipolar disorder and depression. a \$6.75 million fine was also paid to the u.s. government to resolve certain allegations by cms regarding the improper marketing of xibrom. under the settlement agreement, cms is named as a party in a civil lawsuit that was filed in the u. district court for the district of new jersey against ista, b+l, and two executives of ista who are officers of the company, francis a. driscoll and howard i. monserrat.



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upon conviction for the criminal charges described above, ista

will face mandatory exclusion from federal healthcare programs. exclusion will mean that on the effective date of the exclusion, any ista labeled drugs in ista's possession would no longer be reimbursable by medicare, medicaid, or other federal healthcare programs. in june 2012, b+l acquired ista.

simultaneous with the false claims act settlement and the entry of the plea, the u.s. department of health and human services' office of inspector general, ista, and b+l will enter into a divestiture agreement under which ista agrees to be excluded for 15 years, effective six months after the date

of the settlement. under the terms of the divestiture agreement, ista will transfer all assets to b+l or a b+l subsidiary and will stop shipping ista labeled drugs within six months of the divestiture agreement. six months after the effective date of the divestiture agreement, all ista labeled drugs in the possession of

ista or b+l will no longer be reimbursable by medicare, medicaid, and other federal healthcare programs. those ista labeled drugs in the stream of commerce at that time will continue to be reimbursable. but to ensure complete compliance, we will remove your name and other information

from the labels of those drugs, typically to be shipped via air/overnight on the next day's air. we will not be able to remove your name and information from items already out in the stream of commerce at that time. the blue international seed sample certificate (bic) represents only the seed sample that was

tested. the sample is provided by the customer and the certificate does not officially represent the entire seed lot as does the oic. as with the oic, only ista accredited labs can issue the bic, ensuring that the test results themselves are dependable. because there is no sampling restriction, we can

accept and test samples from customers located anywhere. please see the blue certificates page for more detailed information. 5ec8ef588b

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