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OIG Fact Sheet on Forest Laboratories, Inc., and the Inspector General's Exclusion Authorities

May 10, 2011

This fact sheet provides relevant background regarding the Office of Inspector General's (OIG) exclusion authorities and facts related to the criminal convictions of a subsidiary of Forest Laboratories, Inc., to correct some inaccuracies that have appeared in the media.

- The Social Security Act authorizes the Secretary of HHS to exclude persons from participation in Federal health care programs. The authority to exclude has been delegated to the Inspector General for decades. There are many different bases for exclusion. OIG excludes, on average, over 3,000 persons a year.
- OIG is a nonpartisan oversight and enforcement agency. OIG sets its exclusion enforcement policy and determines whom to exclude without direction from the Secretary. OIG informs the Secretary and the Department of Justice of significant exclusion policy decisions or cases.
- Among other things, section 1128(b)(15) of the Social Security Act authorizes the exclusion of any officer or managing employee of a company that has been convicted of certain criminal offenses.
- In October 2010, OIG issued public guidance on factors OIG would consider in determining whether to exclude an officer or managing employee under section 1128(b)(15). (This guidance is available online

at: http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (PDF))

OIG will consider:

- circumstances of the misconduct and seriousness of the offense,
 - individual's role in the company,
 - individual's actions in response to the misconduct, and
 - information about the company.
- The exclusions process includes advance notice and multiple levels of appeal. When OIG is considering excluding someone, OIG sends the person a written notice of intent to exclude. The person has 30 days (this may be extended upon request) to submit a written response, which OIG considers in determining whether to proceed with the exclusion. If OIG decides to exclude, OIG issues a notice of exclusion to the person. If the notice of exclusion is issued, the person has administrative and Federal court appeal rights.
 - In March 2011, Forest Pharmaceuticals, Inc., a wholly owned subsidiary of Forest Laboratories, Inc., was sentenced (after pleading guilty in 2010) for three criminal offenses: (1) distributing a misbranded drug (Celexa); (2) distributing an unapproved new drug (Levothroid); and (3) felony obstruction of an agency proceeding, namely, a regulatory inspection by the Food and Drug Administration relating to Levothroid. Last year, the convicted company and its corporate parent also settled civil False Claims Act allegations related to improper drug marketing and distribution. Forest paid a total of \$313 million to resolve the criminal and civil cases. (More information about this case is available online at: <http://www.justice.gov/opa/pr/2011/March/11-civ-270.html>.)
 - Criminal convictions authorize OIG to exclude corporate officers; civil settlements with no admission of guilt do not.
 - OIG has not excluded Howard Solomon, the Chief Executive Officer of Forest Laboratories, Inc.

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