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Alameda County District Attorney Announces Settlement with Perrigo to Reduce Lead Levels in Infant and Toddler Formula Products

Settlement sets lowest enforceable lead levels in the country for infant and toddler formula

OAKLAND – Alameda County District Attorney Nancy O'Malley, California Attorney General Rob Bonta, along with 9 other district attorneys, announced a settlement today with Perrigo Company, a food manufacturing company, and two of its subsidiaries which will significantly reduce the levels of lead in the company's infant and toddler formula products.

In 2018, a lawsuit was filed against Perrigo after testing showed that its infant and toddler formula products contained levels of lead that exceeded the Proposition 65 warning threshold. Perrigo cooperated fully in the investigation and resolution of this matter. As part of today's settlement, Perrigo will target lead levels of four parts per billion (ppb) for most of these products, levels much lower than applicable guidance levels established for this type of product by any U.S. regulatory authority.

"We are vigilant when it comes to dangerous components in products, especially lead which can have very serious consequences," said DA O'Malley. "When companies and businesses expose consumers to lead, especially in food products for infants and children, they must be held accountable.

"Lead exposure is particularly dangerous for children, whose developing brains and nervous systems are more sensitive to its damaging effects. Impacts of lead exposure in children include behavioral issues, reduced IQ, slowed body growth, hearing problems, and kidney damage. There is widespread scientific consensus that there is no safe level of lead exposure. Ensuring that Perrigo, and other manufacturing business' products are safe for consumption is our ultimate goal," DA O'Malley said.

"Today's settlement sets the lowest enforceable lead levels in the country for infant and toddler formula. This is a win for our children and for their parents, who shouldn't have to worry that the formula they feed their kids might harm their health and development down the line," said Attorney General Bonta. "By agreeing to put ingredient sourcing and quality control processes in place, Perrigo will be able to reduce its lead levels to more than ten times below current federal guidance levels. I hope other companies will take this settlement as evidence that it is possible to reduce the levels of lead in their products — and that if these levels exceed the Prop 65 warning threshold and the companies fail to either reduce the levels or provide a warning, my office won't stand idly by."

The lawsuit alleged that Perrigo violated Proposition 65 and California's Unfair Competition Law by manufacturing products with lead levels that exceeded the Proposition 65 warning threshold. Today's settlement identifies four named products and requires Perrigo to significantly reduce the levels of lead in these and other powdered formula products by:

- Setting a target lead level for all Perrigo infant and toddler formula products sold in California of 4 ppb, with a maximum lead level of 5-7 ppb, depending on the product.
- Requiring Perrigo to put ingredient sourcing and control processes in place, consult with an
 independent food processing auditor, set internal food quality auditing practices, and conduct
 compliance testing to ensure that its products do not exceed the maximum lead level; and
- Ensuring that if a product lot exceeds the maximum lead level and is not found to be an outlier, it is removed from sale in California. In such cases, Perrigo must also investigate the cause of the exceedance, and work with the auditor to keep the level under the maximum.

Besides the Attorney General, District Attorney O'Malley is joined in this action by the district attorneys of Marin, Monterey, Napa, Santa Clara, Santa Cruz, Shasta, Solano, Sonoma, and Orange counties. Also included in the settlement was a parallel lawsuit brought by a Community Science Institute, a private enforcer, which also sought to enforce Proposition 65.

Without admitting liability, Perrigo agreed to pay a total of \$145,000 in civil penalties and \$215,000 in costs and fees.

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