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U.S. Sens. Baldwin, Hoeven: Call on FDA to take action to increase access to baby formula, explain actions to date and recommendations

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WASHINGTON, D.C. – U.S. Senators Tammy Baldwin (D-WI) and John Hoeven (R-ND), Chair and Ranking Member of the Senate Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Subcommittee, sent a letter to FDA Commissioner Dr. Robert Califf to urge the Agency to take all necessary steps to ensure access to this critical product, now and going forward.

"While we appreciate the steps currently being taken by the Food and Drug Administration (FDA), we are concerned that the Agency did not take these actions sooner, and we believe that more must be done to safely alleviate the shortage as quickly as possible," **said the senators.** "Earlier intervention from the FDA to enhance supply chains, in part by utilizing the authorities announced this week, would have mitigated the impact of the loss of a major manufacturing facility and prevented this crisis."

The letter continues to ask for the following:

- "A detailed timeline of the FDA's inspection of the Abbott facility in Sturgis, MI, including dates of inspection and details of problems encountered at the facility by FDA inspectors.
- "A full explanation of the Agency's efforts to ensure that all imported formula meets the same high standards of safety and nutrition required by the FDA of U.S. manufacturers. This should include information as to whether there is manufacturing equivalency in overseas facilities and details regarding how the

FDA will guarantee these products are safe without in person inspections.

- “A complete explanation of actions taken by the FDA to date, and recommendations on how to immediately increase access to infant formula as well as bolster the supply chain.
- “A detailed explanation of actions taken to date and recommendations on how the FDA can work to prevent a similar crisis from occurring in the future.”