US FDA SETS STANDARDS FOR INFANT FORMULA

On 10 February 2014 the United States Food and Drug Administration (US FDA) published their interim final rule on Current Good Manufacturing Practices (cGMPs), Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula.

This interim final rule implements the remaining provisions of the 1986 Anti-Drug Abuse Act which amended Section 412 of the Food Drug and Cosmetic Act (FDC&A). Section 412 of the FDC&A was created by the Infant Formula Act of 1980. Exempt from this rule will be formulas made for infants with unusual medical and dietary problems such as formulas for infants born extremely pre-mature.

CGMPs, QUALITY CONTROL PROCEDURES, AUDITS, QUALITY FACTORS, REGISTRATION, NOTIFICATION, RECORDS AND REPORTS

- One of the cGMPs being required is controls to prevent adulteration by contamination of infant formula from microorganisms requiring testing of powdered infant formula at the final stage for Cronobacter and Salmonella species. Other requirements involve a code that identifies the location of packing and tracing of all stages of the manufacturing process, approved release of finished products and controls to prevent adulteration by contamination during manufacturing or packing from many sources.

<table>
<thead>
<tr>
<th>MICROORGANISM</th>
<th>n¹</th>
<th>SAMPLE SIZE</th>
<th>M VALUE</th>
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<tbody>
<tr>
<td>Cronobacter spp.</td>
<td>30</td>
<td>10 g (grams)</td>
<td>≥0.0</td>
</tr>
<tr>
<td>Salmonella spp.</td>
<td>60</td>
<td>25 g</td>
<td>≥0.0</td>
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¹ Number of samples.
² None detected.

- Quality control procedures are revised to require in-process and final product testing to ensure that all required and added nutrients are present and at appropriate levels. For example, the finished product, before distribution shall be tested for vitamin A, C, E and thiamin.
• Requirements to conduct regularly scheduled audits to determine cGMP and quality control procedure compliance are established.

• The US FDA established two quality factors, the manufacturer is to conduct a growth monitoring study of the formula and conduct a Protein Efficiency Ration rat bioassay to establish biological protein quality.

• There is a registration requirement to provide the US FDA information about the firms producing infant formulas for US distribution. Requirements to provide scientific data and information to the US FDA to demonstrate a new infant formula contains all the required nutrients and meets or the requirements of the rule.

• Records and report requirements are included to support the requirements as listed in this rule such as the microbiological testing requirements.

Comments may be submitted until 27 March 2014 and this rule will become effective 10 July 2014.

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