

28 October 2008
[18-08]

APPLICATION – ADMINISTRATIVE ASSESSMENT

A1017	<p>Date Received: 10 September 2008 Date Due for completion of Administrative Assessment: 1 October 2008 Date Administrative Assessment Completed: 30 September 2008</p>	
<p>Applicant: Forbes Medi-Tech Inc via Food Assist</p>		<p>Potentially Affected Standard in the Code:</p>
<p>Title: Additives for Use in Low- & No-fat Milk with Added Tall Oil Phytosterols</p> <p>Brief Description of Application: To approve the use of hydroxypropyl starch, dextrans (white & yellow, roasted starch) and carrageenan as food additives in low-fat and no-fat liquid milk to which tall oil phytosterols have been added.</p>		<p>Standard 1.3.1 – Food Additives</p>
<p>Procedure: General Reasons why: The Applicant is seeking extension of permissions for use of currently permitted GMP food additives</p>	<p>Cost Category (General Procedure): Up to 500 hours</p> <p>Reasons why: The risk assessment (toxicological, nutritional and dietary modelling assessments) will be of average complexity and risk management options should also be relatively simple.</p>	<p>Estimated start work: If not paid to expedite the Application, the project would be deferred for more than 1 year from the time of receipt due to current work loads.</p>

DECISION

<p>Application rejected</p> <p>Date: 30 September 2008</p> <p>If rejected, list reasons for rejection:</p> <p>The Application does not meet the mandatory information requirements under Part 3 of the <i>Application Handbook</i>, as required under subsection 22(2) of the FSANZ Act.</p>

Has the Applicant claimed Confidential Commercial Information status?

Yes No ✓

What documents are affected? N/A

Has the Applicant provided justification for Confidential Commercial Information status?

Yes No ✓

Is the Application for a High Level Health Claim?

Yes No ✓

If so, has the Applicant made an election to have FSANZ give public notice calling for submissions under s.51 of the FSANZ Act?

Yes No

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together e.g. a novel food and a related high level health claim.

Yes No ✓

Details:

Charges

Does FSANZ consider that the application is subject to ECCB?

Yes No ✓

If yes, indicate the reason:

If yes, indicate due date for fees to be paid (20 business days after notification of Admin Assess made). Note that if fees are not received by this date, the Application is automatically rejected.

Due date for fees: N/A as Application rejected

Does the Applicant want to expedite consideration of this Application?

Yes No Not known ✓

Application Handbook Requirement

Which Guideline/s within the Part 3 of the *Application Handbook* apply to this Application:
3. 1 and 3.3.1

Does the Application meet the requirements of the relevant Guideline/s?

Yes No ✓

Is the checklist completed?

Yes ✓ No

What information is not provided?

FSANZ requires the following further information to meet the requirements of the relevant guidelines (3.1 and 3.3.1) of the *Application Handbook*:

1. further justification for use of the proposed food additives in tall oil phytosterols for use in low-fat and no-fat milk;
2. further information in support of the use of the proposed additives from industry and whether they are used internationally in milks;
3. details of the manufacturing processes;
4. information on the percentage of market share;
5. copies of the most recent safety evaluations on the proposed food additives.

Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?

Yes ✓ No

Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted?

Yes No ✓

Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?

Yes ✓ No

If yes, indicate which Procedure:

General (Level 1)

Other Comments or Relevant Matters:

CONSULTATION & ASSESSMENT TIMEFRAME

Consultation Strategy: Proposed length of public consultation period: General Procedure (6 weeks)	Community Involvement Category: 3 Intensive, narrower focus
Proposed Timeframe for Assessment: N/A	