



**20 August 2008**  
**[15-08]**

**APPLICATION – ADMINISTRATIVE ASSESSMENT**

<b>A1012</b>	<b>Date Received:</b> 9 July 2008 <b>Date Due for completion of Administrative Assessment:</b> 30 July 2008 <b>Date Administrative Assessment Completed:</b> 29 July 2008	
<b>Applicant:</b> Lipid Nutrition B.V.		<b>Potentially Affected Standard in the Code:</b> 1.5.1 – Novel Foods 1.3.4 – Identity and Purity 1.2.3 – Mandatory Warning and Advisory Statements and Declarations 1.2.4 – Labelling of Ingredients
<b>Title:</b> Conjugated Linoleic Acid-Rich Oil as a Novel Food  <b>Brief Description of Application:</b> To approve the exclusive use of Lipid Nutrition’s conjugated linoleic acid (CLA) preparation as a novel food.		
<b>Procedure:</b> General  <b>Reasons why:</b> The earlier CLA exclusive Application, A1005 was considered General which creates a precedent. The request is seeking an exclusive new novel food permission.	<b>Cost Category (General Procedure):</b> Up to 850 hours  <b>Reasons why:</b> The assessment will require detailed toxicological, nutritional and dietary modelling assessments. There will be risk management considerations which may be complex, including labelling and legal drafting.	<b>Estimated start work:</b> August 2008

**DECISION**

<b>Application accepted</b>  <b>Date: 30 July 2008</b>
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<b>Has the Applicant claimed Confidential Commercial Information status?</b> Yes ✓ No
<b>What documents are affected?</b> Appendix 7
<b>Has the Applicant provided justification for Confidential Commercial Information status?</b> 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?**

N/A

**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:** The Applicant is seeking exclusive permission for their Clarinol™ brand of CLA-rich oil as a novel food.

***Charges***

**Does FSANZ consider that the application is subject to ECCB?**

Yes  No

**If yes, indicate the reason:**

The Applicant has sought exclusive use of their CLA preparation as a novel food under clause 3 of Standard 1.5.1.

**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: 26 August 2008 (Received 14 August 2008)**

**Does the Applicant want to expedite consideration of this Application?**

Not applicable since subject to ECCB.

***Application Handbook Requirements***

**Which Guideline within the Part 3 of the *Application Handbook* apply to this Application:**

3.5.2

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

Yes  No

**Is the checklist completed?**

Yes  No

**What information is not provided?**

N/A

**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 2)**

**Other Comments or Relevant Matters:**

**CONSULTATION & ASSESSMENT TIMEFRAME**

<p><b>Consultation Strategy:</b>          Proposed length of public consultation period:          • General Procedure (6 weeks)</p>	<p><b>Community Involvement Category:</b>  <b>3</b>          Intensive, narrower focus</p>												
<p><b>Proposed Timeframe for Assessment:</b></p> <p><b>'Early Bird Notification' due: 21 August 2008</b></p> <p><u>General Procedure:</u></p> <table> <tr> <td>Commence Assessment (clock start)</td> <td>14 August 2008</td> </tr> <tr> <td>Completion of Assessment</td> <td>Early December 2008</td> </tr> <tr> <td>Public comment</td> <td>Mid December 2008 – early February 2009</td> </tr> <tr> <td>Board to complete Approval</td> <td>14 May 2009</td> </tr> <tr> <td>Notification to Ministerial Council</td> <td>Mid-May 2009</td> </tr> <tr> <td>Anticipated gazettal if no review requested</td> <td>Early August 2009</td> </tr> </table>		Commence Assessment (clock start)	14 August 2008	Completion of Assessment	Early December 2008	Public comment	Mid December 2008 – early February 2009	Board to complete Approval	14 May 2009	Notification to Ministerial Council	Mid-May 2009	Anticipated gazettal if no review requested	Early August 2009
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