

**17 October 2020**

**[142-20]**

**Administrative Assessment Report –Application P1214**

Nicotinamide riboside chloride as Vitamin B3 in FSMP

1. **Application details**

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| **Date received:** 9 October 2020  **Date due for completion of administrative assessment:** 2 November 2020  **Date completed:** 2 November 2020 | | |
| **Applicant:** ChromaDex Inc. | | **Potentially affected standard/s:**  *Standard 2.9.5 –* Food for special medical purposes  *Schedule 29-20* – Special Purpose Foods |
| **Brief description of Application:**  Application to amend the Food Standards Code to permit the use of nicotinamide riboside chloride as a permitted form of Vitamin B3 in food for special medical purposes (FSMPs). | |
| **Procedure:**  General | **Estimated total variable hours:**  540 hours  **Reasons why:**  The Application is requesting the addition of a new permitted form of Vitamin B3 for use in FSMPs, requiring detailed safety and efficacy assessments. | **Estimated start date:**  Late November 2020 |

1. **Decision**

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| **Application accepted**  **Date**: 2 November 2020  **If fees for ECCB are not received, date of rejection: 1 December 2020** |

1. **Additional matters**

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| **Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?**  Yes – CCI only  **What documents are affected?**  All information provided by the Applicant in:   * Annex 1 (11 documents) * Annex 2 (14 documents) * Annex 4 (40 documents)   **Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?**  No, all CCI requests relate to whole documents  **Has the Applicant provided justification for why information is CCI or confidential?**  Yes |
| **Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?**  No |

1. **Charges**

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| **Does FSANZ consider that the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant?**  Yes  **Reason:**  The Applicant is the owner of a patent/s in relation to nicotinamide riboside chloride. The Applicant states that they expect to have exclusive control over the distribution of nicotinamide riboside chloride, the subject of this application.  **Due date for fees:** 30 November 2020 |

1. **Assessment against FSANZ Act 1991 requirements**

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| **Subsection 26(2)** |
| **(b) 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 |
| **(c) Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it should not be accepted?**  No |
| **(d) Are there any other matters relevant to the decision whether to accept or reject the application?**  No |

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| **Does the application meet each of the following criteria required by subsection 22(2)?** |
| 1. **The application is in writing**   Yes |
| 1. **The application is in the form specified in guideline 3.1.1 of the Application Handbook**   Yes |
| 1. **The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application.**   Yes – Guidelines 3.1.1, 3.3.3, 3.6.3 |
| **Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**  Yes  **Indicate which Procedure:**  General |
| **Other Comments or Relevant Matters:**  Nil |

1. **Consultation & assessment timeframe**

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| **Proposed length of public consultation period:**  6 weeks |
| **Proposed timeframe for assessment**  ‘Early Bird Notification’ due: 7 December 2020  General Procedure:  Commence assessment (clock start) Early December 2020  Completion of assessment & preparation of draft food reg measure March 2021  Public comment Late April – Early June 2021  Board to complete approval Late August 2021  Notification to Forum Early September 2021  Anticipated gazettal if no review requested Mid-November 2021 |