

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**NOVARTIS NUTRITION CORPORATION**

**I. PREAMBLE**

Novartis Nutrition Corporation (NNC) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, NNC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the Effective Date of this CIA, NNC voluntarily established an Ethics and Compliance with Law Program (the "Compliance Program"), which includes regular training for employees about the Novartis Code of Conduct and provides for a Corporate Compliance Officer, a Compliance Committee, a compliance training and education program, a confidential reporting hotline, a screening methodology for prospective employees, and various policies and procedures aimed at ensuring that NNC's activities are in compliance with all Federal health care program requirements and meeting NNC's goal of promoting high ethical standards in the conduct of NNC's business practices. NNC shall continue the operation of its compliance measures in accordance with the terms of this CIA. NNC may modify its Compliance Program as appropriate, but, at a minimum, shall comply with the integrity obligations enumerated in this CIA. For purposes of clarification, and subject to provisions relating to applicability set forth below, this CIA shall be applicable only to those operations of NNC that relate to products that are reimbursable by Federal health care programs.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by NNC under this CIA shall be five (5) years from the Effective Date of this CIA, unless otherwise specified. The Effective Date shall be the same date as the Effective Date of the Settlement Agreement, into which this CIA is incorporated by reference (Effective Date). Each one-year period, beginning with the first day of the month closest to the Effective Date of this CIA, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) NNC's final Annual Report; or (2) any additional materials submitted by NNC pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:
  - a. all directors and officers of NNC;
  - b. all NNC employees who engage in the marketing or sale of items or services for which reimbursement may be made by the Federal health care programs; and
  - c. all individuals who market or sell, on behalf of NNC, enteral nutrition items or services, including those who perform these functions and are employed by Novartis Medical Health, Inc., with the exception of unrelated third parties that purchase in arms-length transactions and then distribute such items or services, e.g., wholesalers or distributors whose only relationship with NNC is the purchase, distribution, and/or shipping of such items or services.
2. "Relevant Covered Persons" includes all Covered Persons identified in Section II.C.1.b and c, above, who personally engage in the promotion, marketing, or sale, on behalf of NNC, of enteral nutrition items or services for which reimbursement may be made by the Federal health care programs.
3. "Enteral nutrition" means the provision of nutrients directly into the

