MANUFACTURE AND PACKAGING OF

DIETARY SUPPLEMENTS

CODE OF GOOD MANUFACTURING PRACTICE

Health Protection
Department of Health
1988

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FOREWORD

The Department of Health is responsible for the safety and quality of all dietary supplements on sale in New Zealand and also product that is exported. With this in mind the Department of Health has during the last two years held discussions with manufacturers of dietary supplements. The information gained in this time has been used to develop this code of practice which aims to reflect not only the current position but also to provide guidelines for use over the next few years. Any such code has to take account of the nature of the product and manufacturing requirements. It will be used to guide future inspections of manufacturing facilities.

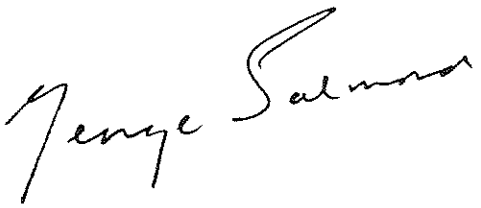
The co-operation of the industry in producing the code is appreciated and in particular the assistance given by the National Nutritional Foods Association and the Proprietary Medicines Federation.

The code is not intended to be an interpretation of legislation. It does not state what is specifically required by law, but rather establishes standards and procedures to be aimed at during the manufacture and packaging of dietary supplements.

No code can be fully comprehensive as the pursuance of good practice and quality is a developing subject and must retain a flexible approach to allow for interpretation as required in individual cases.

The development of this code in co-operation with the National Nutritional Foods Association and the Proprietary Medicines Federation reflects the goodwill between the industry and the Department of Health.

I look forward to the continuation of this relationship since the pursuit of high standards is of concern to all involved in the manufacture of dietary supplements.



George Salmond
Director-General of Health

INDEX

1 INTRODUCTION

The Code of Good Manufacturing Practice for Dietary Supplements is a guideline for manufacturing companies in New Zealand. The code will have no statutory force and is not intended to be an interpretation of legislation. It concerns the manufacturer of dietary supplements which includes vitamin and mineral preparations.

It is important that the methods and controls used for the manufacture and packaging of dietary supplements conform to good manufacturing practice so that the finished product meets the required standard of quality and safety.

The Department of Health will conduct inspections of premises undertaking the manufacture and distribution of dietary supplements.

It is essential that manufacturers shall not rely solely on these inspections to provide quality audits of their premises and operations but have in operation a system of self-inspection. These self-inspections should be documented and should involve senior management in order to indicate the importance of quality control.

2 DEFINITIONS

- A dietary supplement means any acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders or tablets, which are intended to supplement the intake of those substances normally derived from food.
- This definition is in Section 2, Interpretation, of the *Dietary Supplements Regulations 1985* which are administered by the Department of Health.
- A "labile material" refers to material which is likely to deteriorate under prolonged storage or when not stored under specified conditions.

3 PERSONNEL

- Each manufacturing establishment must employ a person possessing adequate technical and practical experience, with the authority and responsibility to ensure and maintain the identity, purity and quality of the products manufactured.
- Personnel responsible for directing manufacture and control shall have the necessary training and experience to assure that the products meet the established requirements and control limits.
- All personnel shall have the necessary training and experience to perform their assigned functions in manufacture and control.
- All personnel coming into contact with the product or packaging should be aware of the importance of good personal hygiene.
- Personnel shall be free from any communicable disease, or open skin lesions on the exposed surface of the body. Any personnel with these conditions shall be excluded from direct contact with materials, equipment or product until the condition is corrected.
- Clean protective clothing including hair coverings should be worn over or in place of normal clothing by all staff and visitors in the processing and packaging areas. The wearing of costume jewellery should be discouraged.
- Staff shall not store personal belongings, eat food, drink beverages or smoke in the manufacturing, packaging, storage and laboratory areas.

4 PREMISES AND FACILITIES

- The premises should be laid out so as to ensure:
  1. Wherever possible there should be segregation of areas used for raw materials, manufacturing, packaging and storage of finished goods. In particular there should be quarantine areas for the following categories of goods
     — raw materials upon receipt
     — goods in process

— rejected or recalled goods awaiting disposal;

2. That cross contamination of products cannot occur in manufacture and packaging and that operations carried out in a particular area of the premises are compatible;
3. That special storage areas for bond stores, and flammable goods are provided as specified in relevant legislation. Access to these areas shall be restricted.

- Adequate hand washing facilities with sufficient hot water, well ventilated toilets and locker facilities must be provided within easy access to the manufacturing and packaging areas. The washing facilities and toilets should be kept clean.
- Methods of disposal of sewage, industrial waste and other refuse must be available and be operating satisfactorily. These methods should comply with local requirements and legislation.
- The building should be kept free of rodents, birds and other pests.
- The building should have adequate lighting and ventilation. The ventilation system should be designed to minimise dust and airborne contamination.
- An adequate water supply that should comply with local requirements and legislation must be available.
- The walls, floors and ceiling in the various areas of the factory shall be made of materials which can be readily cleaned and are designed to facilitate easy cleaning and sanitation.
- The manufacturing area, packaging area, storage and laboratory areas shall be kept clean and in an orderly condition.
- Adequate first aid facilities shall be available in appropriate locations, as specified in the relevant legislation.

5 *SUB-CONTRACTING*

If a distributor or a manufacturer sub-contracts any work covered by this *Code of Good Manufacturing Practice,* then it is the responsibility of the distributor or manufacturer to ensure that the sub-contractor complies with the provisions of this code.

6 *EQUIPMENT*

- Equipment in which products are manufactured must be maintained in a clean condition and must be so constructed as to be capable of easy, efficient cleaning.
- The equipment must be constructed so that all surfaces which come in contact with a product shall not be reactive, additive or absorptive so as to alter the product or its components beyond established control limits.
- All measuring equipment used in production and quality control shall be of the appropriate degree of accuracy for the work being carried out. It shall be calibrated and checked at regular intervals by acceptable methods. Records of such checking shall be kept and be readily available.

7 *PRODUCTION PROCEDURES*

7.1 Raw Materials

- A systematic procedure should be established for the inspection of all incoming raw materials in order to assure the identity and quality of the material.
- Consideration should be given to a system for retention of samples of raw materials for an appropriate period particularly where such materials are critical to the effectiveness or safety of the product.
- Stocks of approved raw materials must be differentiated from those which are not approved.
- A system is required to identify materials at all appropriate stages of manufacture.
- A system should be available to ensure that partly used containers of materials are properly closed, stored, and identified and have not deteriorated. Labile materials shall be retested to ensure that they conform to specifications at the time of use.
- A system should be established to ensure that the oldest raw materials are used first.

- Materials which have been rejected after testing for any other reason must be identified clearly as rejected. Such material shall be physically separated and then either returned to the supplier, destroyed or otherwise disposed of without undue delay. Records shall be maintained on the disposal of any material.

7.2 Packaging and Labelling Materials

- All packaging material shall be examined and approved on receipt.
- All labelling materials, including pre-printed containers, inserts, and pre-printed packaging materials shall be examined and approved on receipt.
- Stocks of approved packaging and labelling materials must be differentiated from those which are not approved.

7.3 Formulation and Manufacturing Instructions

- **Master Manufacturing Records**
  Each product should have a written master formula which should be prepared, endorsed and dated by a competent person to whom this responsibility has been delegated by management. The master document should include where appropriate:
  - — the name and description of the finished product;
  - — a space for the batch or lot number and the date of manufacture;
  - — the name and amount of each raw material expressed by weight or volume whether it appears in the finished product or not;
  - — a statement of the total weight or volume of the batch including reasonable variations and provisions for adjustment when appropriate;
  - — details of each step in the manufacturing process including any special instructions or precautions;

  - — quality control parameters and any testing to be carried out during processing.
- **Batch Manufacturing Records**
  A copy of the appropriate master formulation and manufacturing instructions shall be made for each batch of a product before it is manufactured. The copying shall preferably be done by photocopying in order to minimise the possibility of transcription error. If photocopying is not possible each copy shall be signed by a responsible person designated by management to indicate that it has been checked for accuracy. The manufacturing documents shall include the following records:
  - — either initials or indications that the individual raw materials have been measured and added to the batch;
  - — the date of manufacture;
  - — a number, either a control code or the equivalent which uniquely identifies the batch at all stages of manufacturing. This number should also permit identification of the batch during in-process testing and subsequently any quality control testing;
  - — the number of containers for each batch together with the actual weight or volume of the batch.

7.4 Packaging and Labelling Instructions

- **Master Packaging and Labelling Records**
  Each product and pack size should have a written master packaging instruction which should be prepared, endorsed and dated by a competent person to whom this responsibility has been delegated by management. The master document should include where appropriate:
  - — the name and description of the product and the weight or volume in the final pack;
  - — a space for the batch or lot number and the expiry date;
  - — a description of all the materials required to package and label the product;

— details of any special instructions or precautions for the packaging and labelling of the product;

— quality control parameters and any testing to be carried out during packaging.

- **Batch and Packaging and Labelling Records**
  Where a packaging run constitutes an individual batch or a product, a copy of the appropriate master packaging and labelling instructions shall be made for each batch of a product before it is packed. The copying shall preferably be done by photocopying in order to minimise the possibility of transcription error. If photocopying is not possible each copy shall be signed by a responsible person designated by management to indicate that it has been checked for accuracy. The packaging documents shall include the following records:

  — either initials or indications that all packaging and labelling materials have been checked for identity and conformity to the specifications in the packaging records prior to packaging;

  — the date of packaging;

  — the batch number. Different filling lots shall be distinguishable;

  — the expected number of each packaging size to be packaged and labelled;

  — the actual number of each packaging size packed and labelled;

  — an example, where practical of the label and unit carton which show all details on the retail pack.

- Where a packaging run constitutes processing of a continuous number of batches, a procedure should be available to ensure each fill lot complies with the master packaging instruction and to enable specific complaints to be traced back to specific batch numbers.

7.5 Production and Packaging Control

- At all times during production, all bulk containers shall be adequately labelled so that the contents may be identified by name and production batch number. When necessary, the stage of production should be recorded on the container or label.
- Procedures must be established to ensure that equipment, packaging lines and tables are clean and free from any materials not relevant to the current operation.
- The actual yield of each production batch packed should be checked against the estimated theoretical yield.
- At the completion of manufacturing and packaging of each batch, all records of production and packing shall be examined to ensure compliance with the production, packaging and labelling instructions.
- All relevant records should be retained for a minimum period of one year after product expiry date.
- Bulk materials remaining after completion of a packaging run should be stored in sealed vessels and properly labelled. Where appropriate, instructions for retesting should be included on the label.
- A system of ensuring that the oldest batches of finished goods are despatched first should be established.

8 QUALITY ASSURANCE

- A quality control laboratory shall be available which is fitted with sufficient equipment to carry out all the necessary assays and tests. Contract laboratories may be used.
- A quality assurance programme which is concerned with obtaining and maintaining the required quality is essential in manufacturing. Ideally this should be supervised by a person responsible directly to an appropriate level of management and independent of other responsibilities in the manufacturing operation.

- The manufacturing and quality assurance personnel should be consulted before any changes are made in the manufacturing procedures or in the written instructions.
- Adequate physical, chemical and microbiological control specifications for raw materials, intermediate products and finished products should be established by the quality assurance department.
- The quality assurance department will be empowered to take samples from any part of the premises at any time.
- In the case of finished products, samples of sufficient size should be retained to permit re-examination and to investigate any possible complaint. The sample retention time should be one year past the expiry date of the product.
- The quality control department shall keep appropriate analytical records relating to the quality of each batch manufactured. These records shall include:
  - — an evaluation as to whether the batch conforms to the established specifications;
  - — the initials of the person who has performed the quality control procedures.
- There shall be procedures to ensure that only a fully approved product is released from production and packaging.
- The quality control department shall be responsible for the examination of certain categories of returned goods to determine whether such goods should be released, reprocessed or destroyed. Records should be maintained of the evaluation of any complaint and the action taken.

9 CLEANING AND SANITATION

- The importance of general hygiene especially in the manufacturing, packaging and storage areas should be stressed to all staff. Where appropriate, written cleaning methods and instructions which also define the frequency of cleaning should be available to staff. Training sessions on cleaning procedures or requirements should be given to new staff members.

10 IMPORTS

- Any importer, (or their agent or representation) of dietary supplements which are sold in New Zealand shall comply with the *Dietary Supplements Regulations* (the relevant sections of) and the *GMP Code for the Manufacture and Packaging of Dietary Supplements.*

11 EXPIRY DATING

- Each manufacturer or distributor of dietary supplements will generate stability data for each product relevant to the retail pack in which the product is sold in New Zealand.

  In addition a programme should be instituted to ensure that this data is updated on an ongoing basis.

12 RECALLS

- A predetermined system of product recall shall be available. The Department of Health shall be consulted whenever a dietary supplement recall is under consideration and the reasons for the recall shall be fully discussed with the department.