

August 8, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville Maryland 20852



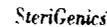
Food Safety Division

Rick Doscher
Director, Quality Assurance

6000 Poplar Avenue, Suite 426, Memphis, TN 38119 ☐ Tel. (901) 681 9006
Fax: (901) 681 9007 ☐ rdoscher@iba-group.com ☐ Website: <http://www.iba.be>

Dear Sir or Madam,









Re: Program Priorities for CFSAN

IBA owns and operates 17 irradiation facilities in the United States. While most of our facilities process medical and consumer health products, several also process food and cosmetic ingredients. So, we are regulated and inspected by FDA, only irradiate food when FDA approves it and provide services that improve consumer health and safety.

Our thinking about program priorities for CFSAN was complicated because CFSAN has not indicated which work items for fiscal 2001-2002 were completed. There were several items in the 2002 work plan that we were very interested in and would like to see completed. For example:

2.1.3 to make lawful the addition of dietary supplements to food. We believe this is both sensible and could improve public health. From a processing perspective, we hope FDA will approve the irradiation of dietary supplement ingredients to ensure that, if they are added to food, they do not diminish food safety.

2.3.3 Publish a proposed rule for GMP for dietary supplements. For irradiation to be most effective it is very important that food and dietary ingredients be manufactured with GMP, yet they are not yet defined for dietary supplements. Dietary supplements and dietary ingredients are being consumed by more people, and manufactured by more manufacturers. The lack of defined GMP is a risk to consumer health and makes our work with potential customers more difficult.

2.3.4 Standardize dietary supplement common names. This would help our industry to understand inquiries from prospective customers for irradiation services. It would be helpful if the list of common names were to be associated with the Latin names for the plant materials.

2.3.4 Prepare a regulatory guideline for dietary supplements. This would help us to understand and follow the regulations, since the regulations in the field of dietary supplements seem more complex than most and are covered by more than one piece of legislation.

2.4.2 Update the 1992 Cosmetic Handbook. We currently process some cosmetic ingredients. Although we use the 1992 Handbook, it would assist our work if this document were updated.

98N-0359

C 76



Food Safety Division

If these work items have already been completed, could you please send the finished reports to us. If not, we request that they remain high priorities for fiscal 2002-2003.

The 2002 work plan noted a strengthened emphasis on food security. While no one would deny the need to ensure Americans are not deliberately harmed via the food supply, we note with dismay that emphasis on food safety seems diminished.

Foodborne microorganisms present a serious, clear, demonstrable and largely preventable risk to consumers and to public confidence in the food supply. Public health statistics continue to show that foodborne bacteria, viruses and parasites cause millions of dollars of economic costs and overwhelming human suffering each year. Irradiation is a process that can lessen or eliminate the risk from many foodborne microorganisms. We feel that more resources and priority should be given to reviewing, conducting related research and preparing regulations for the numerous food irradiation, food safety petitions. The 2002 work plan gives performance standards for the quick approval of color additives and we would prefer that FDA publish and follow performance standards for reviews of food safety petitions.

We note Congress has acknowledged that FDA needs more resources to enable its work in food security. We strongly believe that preventing foodborne illnesses through irradiation is part of that effort.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Richard Doscher'.

Richard Doscher
Director of Quality Assurance



August 8, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville Maryland 20852

Dear Sir or Madam,

Re: Program Priorities for CFSAN

IBA owns and operates 17 irradiation facilities in the United States. While most of our facilities process medical and consumer health products, several also process food and cosmetic ingredients. So, we are regulated and inspected by FDA, only irradiate food when FDA approves it and provide services that improve consumer health and safety.

Our thinking about program priorities for CFSAN was complicated because CFSAN has not indicated which work items for fiscal 2001-2002 were completed. There were several items in the 2002 work plan that we were very interested in and would like to see completed. For example:

2.1.3 to make lawful the addition of dietary supplements to food. We believe this is both sensible and could improve public health. From a processing perspective, we hope FDA will approve the irradiation of dietary supplement ingredients to ensure that, if they are added to food, they do not diminish food safety.

2.3.3 Publish a proposed rule for GMP for dietary supplements. For irradiation to be most effective it is very important that food and dietary ingredients be manufactured with GMP, yet they are not yet defined for dietary supplements. Dietary supplements and dietary ingredients are being consumed by more people, and manufactured by more manufacturers. The lack of defined GMP is a risk to consumer health and makes our work with potential customers more difficult.

2.3.4 Standardize dietary supplement common names. This would help our industry to understand inquiries from prospective customers for irradiation services. It would be helpful if the list of common names were to be associated with the Latin names for the plant materials.

2.3.4 Prepare a regulatory guideline for dietary supplements. This would help us to understand and follow the regulations, since the regulations in the field of dietary supplements seem more complex than most and are covered by more than one piece of legislation.

2.4.2 Update the 1992 Cosmetic Handbook. We currently process some cosmetic ingredients. Although we use the 1992 Handbook, it would assist our work if this document were updated.

98N-0359

C 76



If these work items have already been completed, could you please send the finished reports to us. If not, we request that they remain high priorities for fiscal 2002-2003.

The 2002 work plan noted a strengthened emphasis on food security. While no one would deny the need to ensure Americans are not deliberately harmed via the food supply, we note with dismay that emphasis on food safety seems diminished.

Foodborne microorganisms present a serious, clear, demonstrable and largely preventable risk to consumers and to public confidence in the food supply. Public health statistics continue to show that foodborne bacteria, viruses and parasites cause millions of dollars of economic costs and overwhelming human suffering each year. Irradiation is a process that can lessen or eliminate the risk from many foodborne microorganisms. We feel that more resources and priority should be given to reviewing, conducting related research and preparing regulations for the numerous food irradiation, food safety petitions. The 2002 work plan gives performance standards for the quick approval of color additives and we would prefer that FDA publish and follow performance standards for reviews of food safety petitions.

We note Congress has acknowledged that FDA needs more resources to enable its work in food security. We strongly believe that preventing foodborne illnesses through irradiation is part of that effort.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Richard Doscher'.

Richard Doscher
Director of Quality Assurance



1700 N. Airport Rd.
West Memphis, AR 72301



Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852