specific dates and times established in
advance by the Notice to Airmen. The
effective time will thereafter be continuously
published in the Airport/Facility Directory.

**Paragraph 6000** Class E Airspace Areas
Extending Upward From the Surface of the
Earth

* * * * *

ASW NM E Clovis, NM [Revised]
Cannon AFB, NM
Lat. 34° 22'58" N, Long. 103° 19'20" W
Cannon ILS Localizer
Lat. 34° 22'25" N, Long. 103° 20'09" W
Cannon TACAN0
Lat. 34° 22'51" N, Long. 103° 19'21" W

That airspace extending upward from the
surface within a 6-mile radius of Cannon
AFB. The Class E airspace area is effective
during the specific dates and times
established in advance by the Notice to
Airmen. The effective time will thereafter be
continuous published in the Airport/Facility
Directory.

* * * * *

Issued in Fort Worth, TX, on August 1, 2006.

Donald R. Smith,
System Support Group Manager, Central Service Area.

[FR Doc. 06–6910 Filed 8–17–06; 8:45am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2002F–0316 (formerly 02F–
0316)]

Food Additives Permitted for Direct
Addition to Food for Human
Consumption; Bacteriophage
Preparation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the
food additive regulations to provide for the safe use of a bacteriophage
preparation on ready-to-eat meat and
poultry products as an antimicrobial
agent against *Listeria monocytogenes*. This action is in response to a petition
filed by Intralytix, Inc.

DATES: This rule is effective August 18, 2006. Submit written or electronic
objections and requests for a hearing by
September 18, 2006. See section VII of
this document for information on the
filing of objections. The Director of
the Office of the Federal Register approves the incorporation by reference in

accordance with 5 U.S.C. 552(a) and 1
CFR part 51 of certain publications in
new 21 CFR 172.785 as of August 18,
2006.

ADDRESS: You may submit objections
and requests for a hearing, identified by
Docket No. 2002F–0316 (formerly 02F–
0316), by any of the following methods:

Electronic Submissions

Submit electronic objections in the
following ways:

- Federal eRulemaking Portal: http://
  regulations.gov. Follow the
  instructions for submitting comments.
- Agency Web site: http://
  fda.gov/dockets/ecomments.
  Follow the instructions for submitting
  comments on the agency Web site.

Written Submissions

Submit written objections in the
following ways:

- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:
  Division of Dockets Management (HFA–
  305), Food and Drug Administration,
  5630 Fishers Lane, rm. 1061, Rockville,
  MD 20852.

To ensure more timely processing of
objections, FDA is no longer accepting
objections submitted to the agency by e-
mail. FDA encourages you to continue
submitting objections by using the
Federal eRulemaking Portal or the
agency Web site, as described in the
Electronic Submissions portion of this
paragraph.

Instructions: All submissions received
must include the agency name and
Docket No(s). and Regulatory
Information Number (RIN) (if a RIN
number has been assigned) for this
rulemaking. All objections received will
be posted without change to http://
www.fda.gov/ohrms/dockets/
default.htm, including any personal
information provided. For detailed
instructions on submitting objections,
see the “Objections” heading of the
SUPPLEMENTARY INFORMATION
section of this document.

Docket: For access to the docket to read
background documents or objections
received, go to http://
www.fda.gov/ohrms/dockets/
default.htm and insert the docket
number, found in brackets in the
heading of this document, into the
“Search” box and follow the prompts
and/or go to the Division of Dockets
Management, 5630 Fishers Lane, rm.
1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Raphael A. Davy, Center for Food Safety
and Applied Nutrition (HFS–265), Food
and Drug Administration, 5100 Paint
Branch Pkwy., College Park, MD 20740,
301–436–1272.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal
Register of July 22, 2002 (67 FR 47823),
FDA announced that a food additive
petition (FAP 2A4738) had been filed by
Intralytix, Inc., c/o Lewis & Harrison,
122 C St. NW., suite 740, Washington,
DC 20001, now represented by Keller &
Heckman LLP, 1001 G St., NW., suite
500 West, Washington, DC 20001. The
petition proposed to amend the food
additive regulations to provide for the
safe use of a mixture of bacteriophages1
(phages) as an antimicrobial agent
against *Listeria monocytogenes* (*L.*
*monocytogenes*) on foods, including
fresh meat, meat products, fresh poultry,
and poultry products. On December 18,
2003, the petitioner amended the
petition to limit the petitioned use to
ready-to-eat (RTE) meat and poultry
products only.2

The food additive consists of a
mixture of equal proportions of six
individually purified phages. The
petitioner’s rationale for incorporating
multiple phages in one formulation is to
minimize the possibility of *L.*
*monocytogenes* developing a resistance
to the additive. Each phage in the
additive is specific against various *L.*
*monocytogenes* strains, including those
strains known to be associated with
foodborne illness (e.g., *L.*
*monocytogenes* strains, serotypes 1/2a,
4b and 1/2b). The phages are lytic3
double-stranded DNA phages. The
petitioner has characterized each phage with respect to physical properties and
other appropriate identifying factors
(e.g., host range, structural protein
profile, and DNA sequence of complete

1 Bacteriophages are viruses that infect bacteria
only.

2 Ready-to-eat products, as used in this final rule,
are defined in 9 CFR 430.1.

3 Lytic bacteriophages lyse (destroy) their host
bacteria as a normal part of their life cycle without
integrating into the host genome.

4 Genome means the genetic content of a cell or virus.
bacteriophages are specific to L. monocytogenes only. Therefore, FDA concludes that the food additive under consideration does not present a toxicological concern for use in food as proposed by the petitioner based upon the explanations provided in the following sections (Refs. 1 and 3).

B. Safety Evaluation of Potential Residue Components From L. monocytogenes

FDA considered the possibility that the proposed food additive may contain L. monocytogenes components as residues from use of the organism as host for phage multiplication in the manufacturing process. Such residues may include the toxin Listeriolyisin O (LLO). Potential residues of L. monocytogenes other than LLO do not present a safety concern (Ref. 1). Based on our review of scientific literature on the pathogenicity of L. monocytogenes (Ref. 1), FDA finds that LLO is the only substance known to be toxic that may potentially be present as a residue in this food additive after the manufacturing process.

LLO was not detected in the finished food additive within the assay limits of detection of 5 hemolytic units\(^6\) (HU)/ml, and the petitioner provided information on the purification process used in the production of the food additive as additional assurance that LLO would not be present at detectable levels in the finished food additive. Nevertheless, the agency has calculated a worst-case exposure to LLO from consumption of food products treated with the phage preparation. Assuming LLO is present at a maximum level of 5 HU/ml in the additive, the worst-case exposure to LLO for males aged 20 years or more that consume RTE foods treated with the additive at the maximum intended use level is 52 HU/person/day (HU/p/d) at the mean and 104 HU/p/d at the 90th percentile. Males aged 20 years or more represent the worst-case scenario because this population group consumes the highest amount of food intended to be treated with the additive (Ref. 2). In this safety evaluation, FDA reviewed all available information on the identity, toxicity, and the stability of LLO. Even if LLO were present at the level of 5 HU/ml, this level does not present a toxicological concern for the following reasons (Ref. 1):

1. Inactivation of LLO by Cholesterol

The toxicity of LLO has been shown to be significantly reduced (by as much as 200- to 2000-fold) following pre-incubation of LLO with added cholesterol in vitro (Ref. 1). Since the phage preparation will be used on meat and poultry products and these products normally contain significant (milligram) amounts of cholesterol, then any residual amounts of LLO at levels no greater than 5 HU/ml that may be present in the additive are likely to be inactivated by the cholesterol.

2. pH and LLO Activity

Studies show that LLO activity is lost or significantly decreased in acidic (low pH of less than 4) environments (Ref. 1). Residual amounts of LLO, if present, are likely to be inactivated by the low pH (less than 4) within the human stomach.

3. Inactivation of Orally Consumed LLO by Human Defense Mechanisms

In vivo studies demonstrate that both normal intestinal microflora and cell-mediated immunity reactions in the intestines inhibit LLO (Ref. 1). These defense mechanisms provide some protection against low incidental oral exposures to LLO (no greater than 5 HU/ml). Additionally, at these levels, LLO is expected to be rapidly and irreversibly degraded by proteolytic enzymes that may be present in the diet or in the stomach. Thus, LLO at these residual levels would not pose a toxic threat to humans.

Considering all of the above factors, FDA concludes that potential residues of LLO that may be found in the food additive are negligible (5 HU/ml or less) and do not pose a safety concern for the use of the additive as an antimicrobial agent on RTE meat and poultry products.

Although LLO was not detected in the food additive, the agency concludes that a specification is necessary to ensure that LLO is not present in detectable amounts to ensure the purity and safe use of the petitioned food additive. Thus, the agency is including in this regulation a specification of not more than 5 HU/ml for LLO (the limit of detection for the method).

C. Undesirable Genes (Bacterial Toxin Genes) Potentially Carried by Phages

Lysogenic phages, as opposed to those that are lytic, have the capacity to integrate into the host genome and may facilitate transfer of toxin or drug resistance genes between bacterial cells. FDA has determined that the phages contained in the petitioned food additive are lytic based on the petitioner’s information on host lysis...
characteristics and on genomic analysis of each phage (Ref. 4). Therefore, FDA concludes that the use of this food additive would not result in the spread of toxin or drug genes.

D. The Need for Other Specifications

We are also including specifications for potency, absence of undesirable genes, phage titer, absence of L. monocytogenes and other microbiological pathogens, and total organic carbon (Ref. 2). These specifications ensure the identity and safe use of the additive.

III. Other Considerations

FDA recognizes that while this rule is issued under the authority of the Federal Food, Drug, and Cosmetic Act, use of the ingredient must also comply with the Federal Meat Inspection Act or the Poultry Products Inspection Act, which are administered by the U.S. Department of Agriculture (USDA). In particular, those statutes provide that the ingredient must be suitable for its intended use. FDA recognizes that there may be meat or poultry products considered RTE for which use of the additive may not be suitable within the meaning of those statutes. This regulation addresses only the safety standard under section 409 of the Federal Food, Drug, and Cosmetic Act and does not address requirements for suitability administered by the USDA.

IV. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of a phage preparation as an antimicrobial agent against L. monocytogenes on RTE meat and poultry products. Based on this information, the agency concludes that the proposed use of the additive is safe. Therefore, the regulations in part 172 (21 CFR part 172) should be amended as set forth in this document.

In accordance with §171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in §171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 2A4738 (67 FR 47823). No new information or comments have been received that would affect the agency’s previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically state failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.


2. Memorandum dated April 11, 2005, from Division of Petition Review, Chemistry Review Group, Hyo Young Lee, to Regulatory Group II, R. Davy, entitled “FAP 2A4738 (MATS#1137 M 2.3), Petition for the use of LMP–102TM—a mixture of several monoclonal bacteriophages as an antimicrobial agent in ready-to-eat meat and poultry, Submissions of 10/25/04, 1/18/05, 1/25/05, and 2/18/05.”


List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:


2. Section 172.785 is added to subpart H to read as follows:


The additive may be safely used as an antimicrobial agent specific for Listeria monocytogenes (L. monocytogenes) in accordance with the following conditions:

(a) Identity. (1) The additive consists of a mixture of equal proportions of six different individually purified lytic-type (lacking lysogenic activity) bacteriophages (phages) specific against L. monocytogenes.

(2) Each phage is deposited at, and assigned an identifying code by, a scientifically-recognized culture collection center, and is made available to FDA upon request.

(3) The additive is produced from one or more cell cultures of L. monocytogenes in a safe and suitable nutrient medium.

(b) Specifications.

(1) The additive achieves a positive lytic result (OD900 ≤ 0.06) when tested

10 A term that refers to the number of phage particles per milliliter of phage solution.
against any of the following *L. monocytogenes* isolates available from American Type Culture Collection (ATCC): ATCC 35152 (serogroup 1/2a), ATCC 19118 (serogroup 4b), and ATCC 15313 (serogroup 1/2b). The analytical method for determining the potency of the additive entitled “Determination of Potency of LMP—102™,” dated October 9, 2003, and printed by Intralytix, Inc., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

2) The mean phage titer of each monophag in the additive is 1 x 10⁹ plaque forming units (PFU)/ml. The analytical method for determining phage titer entitled “Method to Determine Lytic Activity/Phage Titer,” dated June 6, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

3) The phages present in the preparation must not contain a functional portion of any of the toxin-encoding sequences described in 40 CFR 725.421(d). No sequences derived from genes encoding bacterial 16S ribosomal RNA are present in the complete genomic sequence of the phages.

4) *L. monocytogenes* toxin, listerioliysin O (LLO), is not greater than 5 hemolytic units [HU]/ml. The analytical method for determining LLO entitled “Quantitation of Listeriolysin O Levels in LMP—102™,” dated September 27, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.


6) The additive is negative for gram-positive and gram-negative bacteria capable of growing in commonly used microbiological media (e.g., Luria-Bertani (LB) medium), including *Escherichia coli*, *Salmonella* species and coagulase-positive *Staphylococci*, as determined by the “Method to Determine Microbial Contamination,” dated July 11, 2003, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

7) Total organic carbon (TOC) is less than or equal to 36 mg/kg. The analytical method for determining TOC entitled “Determination of Total Organic Carbon by Automated Analyzer,” dated March 30, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(c) Conditions of use. The additive is used in accordance with current good manufacturing practice to control *L. monocytogenes* by direct application to meat and poultry products that comply with the ready-to-eat definition in 9 CFR 430.1. Current good manufacturing practice is consistent with direct spray application of the additive at a rate of approximately 1 mL of the additive per 500 cm² product surface area.


Jeffrey Shuren, Assistant Commissioner for Policy.

[FR Doc. E6–13621 Filed 8–17–06; 8:45 am]

BILLING CODE 4160–01–S

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 100

Debt Collection Procedures

AGENCY: National Labor Relations Board (NLRB).

ACTION: Interim Rule with request for comments.

SUMMARY: The National Labor Relations Board (NLRB) is issuing interim regulations with a request for comments concerning the procedures used to collect debts that are owed to the NLRB. These interim regulations conform to the legislative changes enacted in the Debt Collection Improvement Act of 1996 (DCIA) and the amended procedures presented in the Federal Claims Collection Standards (FCCS) issued by the Department of the Treasury (Treasury) and the Department of Justice (DOJ). These regulations are intended to improve the NLRB’s collection of debts owed to the United States.

DATES: This interim rule is effective on August 18, 2006. Comments must be received on or before October 17, 2006.

ADDRESSES: You may submit comments, identified by [RIN Number], by any of the following methods:

• Mail: For paper, disk, or CD-ROM submissions, mail to Lester A. Heltzer, Executive Secretary, 1099 14th Street NW., Room 11610, Washington, DC 20570.

• E-mail: Lester.Heltzer@nlrb.gov. Include [RIN Number] in the subject line of the message.

• Fax: Office of the Executive Secretary Fax Number: (202) 273–4270.

Instructions: All submissions received must include the NLRB’s name and the Regulatory Information Number (RIN) for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Lester A. Heltzer, Executive Secretary, National Labor Relations Board, Room 11610, 1099 14th Street, NW., Washington, DC 20570–0001, Telephone (202) 273–1067, e-mail address Lester.Heltzer@nlrb.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On April 26, 1996, the Debt Collection Improvement Act (DCIA) of 1996 (Pub. L. 104–134) was enacted. This Act enhances the Federal Government’s debt collection activities. The purposes of the Act are—

1) To maximize collections of delinquent debts owed to the Government by ensuring quick action to enforce recovery of debts and the use of all appropriate collection tools,

2) To minimize the costs of debt collection by consolidating related functions and activities and using interagency teams,

3) To reduce losses arising from debt management activity by requiring proper screening of potential borrowers, aggressive monitoring of all accounts, and sharing of information within and among Federal agencies,

4) To ensure that the public is fully informed of the Federal Government’s debt collection policies and that debtors are aware of their obligations to repay amounts owed to the Federal Government,

To ensure that debtors have all appropriate due process rights, including the ability to verify,