

MAY 24 2000

# FREEDOM OF INFORMATION SUMMARY

Public Master File 5671

Ceftiofur Sodium

“...for the treatment of respiratory disease (pneumonia) associated with *Pasteurella (Mannheimia) haemolytica* and/or *Pasteurella multocida* in goats.”

Sponsored by:

NRSP-7

PMF 5671

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**FREEDOM OF INFORMATION SUMMARY****I. GENERAL INFORMATION**

Public Master File No. 5671

Sponsor: NRSP-7 Minor Use Animal Drug Program  
Western Region  
University of California  
Davis, California 95616

Generic Name: Ceftiofur sodium sterile powder

Marketing Status: Prescription

**II. INDICATION FOR USE**

For the treatment of goat respiratory disease (pneumonia) associated with *Pasteurella (Mannheimia) haemolytica* and/or *Pasteurella multocida*.

**III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE**

- A. Dosage Form: Powder for reconstitution and injection.
- B. Route of Administration: Intramuscular injection.
- C. Recommended Dosage: 0.5 to 1.0 mg/lb body weight. Treatment should be repeated at 24-hour intervals for 3 consecutive days. Additional treatments may be given on Days 4 and 5 for animals that do not show a satisfactory response after initial 3 treatments.

**IV. EFFECTIVENESS**

A summary of pivotal pharmacokinetic studies demonstrating the effectiveness of ceftiofur sodium in goats is provided. The purpose of these studies was to show that the pharmacokinetics of the drug in goats are similar to those in cattle and sheep for whom the drug is already approved.

- A. Type of Study: "Ceftiofur sodium in goats: Pharmacokinetics of ceftiofur and metabolites after single intravenous and intramuscular administrations of ceftiofur sodium at doses of 1.1 and 2.2 mg Ceftiofur Free Acid Equivalents/kg."

B. Name and Address of Investigators:

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C. General Design of Investigations:

- (1) The purpose of the study: To demonstrate the pharmacokinetics of injectable ceftiofur sodium in goats. By demonstrating comparable pharmacokinetics with those in cattle and sheep, effectiveness may be accepted for the same disease syndrome in goats. There were 3 parts to the study design.

Part 1 - a "single dose crossover study". This portion of the study was designed to provide a comparison of ceftiofur sodium pharmacokinetics following intravenous (IV) versus intramuscular (IM) administration

Part 2 - a "multiple dose administration study". The objective of this study was to confirm the constancy of ceftiofur pharmacokinetics upon multiple IM administrations, regardless of dosage level.

Part 3 - "effect of lactation on ceftiofur pharmacokinetics". The goal of this study was to compare the pharmacokinetic values obtained from goats after lactation with the same data obtained from the same animals in Part 1.

- (2) Test Animals: Twelve lactating dairy goats of various breeds (46 to 71 kg body weight at the initiation of the study). Goats were housed in outdoor pens with shelters at the University of California Dairy Goat Facility. Each goat had a unique ear tag number for identification.

- (3) Treatment Groups: The 12 goats were divided into 4 treatment groups.

Single Dose Crossover Study: Groups 1 and 3 were dosed with ceftiofur sodium at 1.1 mg ceftiofur free acid equivalents (CFAE)/kg. Groups 2 and 4 were dosed with 2.2 mg CFAE/kg. Each animal received both an intravenous dose and an intramuscular dose using a complete two-route, two-period crossover design, with a two-week washout between injections.

Multiple Dose Administration Study: Groups 1 and 3, and groups 2 and 4 were combined. Two weeks after the last injection in the crossover study, the goats were dosed with Ceftiofur sodium intramuscularly for 5 consecutive days at either 1.1 (groups 1 and 3) or 2.2 mg CFAE/kg (groups 2 and 4). Blood was sampled during the five treatment days plus an additional twenty-four hours after dosing. Milk was sampled for the five treatment days plus an additional seven days after dosing.

Effects of Lactation Study: The goats from groups 2 and 4 were taken off feed for three days to stop lactation. After a five-week washout period, they were treated with a single IV dose of 2.2 mg CFAE/kg and blood was sampled at frequent intervals over the subsequent 24 hour period.

- (4) Dosage Form: Ceftiofur sodium for injection reconstituted with 20.0 mL of sterile water for injection, according to label directions resulting in a solution containing 50 mg/mL. A fresh vial was prepared not more than 4 hours prior to use.
- (5) Route of Administration: Intramuscular or intravenous injection.
- (6) Dosages Used: 1.1 or 2.2 mg CFAE/kg.
- (7) Parameters: Blood samples (as described below)  
Milk samples (as described below)  
Physical examination – daily

Study 1: The IV dose blood samples were taken just prior to dosing (time zero) and at 10, 15, 20, 30, 45 and 60 minutes, and at 1.5, 2, 3, 4, 6, 8, 12, and 24 hours post dose. Following the IM administration, blood samples were taken at 0, 10, 20, 30, 45, 60 minutes, and 1.5, 2, 3, 4, 6, 8, 12, and 24 hours post dose.

Study 2: Blood samples were taken at hours 0, 1, 2, 4, 8, and 12 following each daily dose. Blood samples were also collected at hours 24, 30, and 36 following the final administration. Milk samples were collected from each goat twice daily for the three days prior to drug administration, for the 5 days of the study, and for seven days following the last dose. Milk was commingled from both halves of the udder and frozen until assay. Standards were made in control goat milk and frozen to control for stability.

Study 3: Blood samples were taken from each goat just prior to drug administration and at 10, 15, 20, 30, 45, and 60 minutes, and at 1.5, 2, 3, 4, 6, 8, 12, 24, 30, 36 and 48 hours post dose.

## C. Results:

## (1) Blood samples:

Pharmacokinetic analysis of the data was conducted via compartmental procedures using an RSTRIP weighted least squares nonlinear regression software package. All pharmacokinetic equations were fitted to the data using a weighting factor of  $1/\text{concentration}^2$ .

Table 1: Pharmacokinetic values obtained from serum concentrations of ceftiofur and metabolites after intravenous administration of a single dose of ceftiofur sodium at a dose of 1.1 mg ceftiofur free acid equivalents/kg (0.05 mg/lb) in lactating dairy goats.

Parameter	Animal Number						Mean	Std. Dev.
	1061	9079	9063	2032	8026	9055		
$T_{1/2\alpha}$ (min)	26.5	37.1	16.9	36.4	58.0	21.9	28.0	(harmonic)
$T_{1/2\beta}$ (min)	131	166	137	223	389	145	172	(harmonic)
$Cp_0$ ( $\mu\text{g/mL}$ )	8.05	6.81	9.79	7.81	8.18	7.06	7.96	1.1
$AUC_{0 \rightarrow \text{inf}}$ ( $\mu\text{g} \cdot \text{min/mL}$ )	551	681	762	723	1130	797	774	195
$MRT_{0 \rightarrow \text{inf}}$ (min)	122	165	160	192	305	182	188	62

Table 2: Pharmacokinetic values obtained from serum concentrations of ceftiofur and metabolites after intravenous administration of a single dose of ceftiofur sodium at a dose of 2.2 mg ceftiofur free acid equivalents/kg (1.0 mg/lb) in lactating dairy goats.

Parameter	Animal Number						Mean	Std. Dev.
	2025	9047	9039	9048	2058	0003		
$T_{1/2\alpha}$ (min)	46.0	32.9	54.1	69.4	26.9	45.7	41.6	(harmonic)
$T_{1/2\beta}$ (min)	230	164	305	505	182	221	233	(harmonic)
$Cp_0$ ( $\mu\text{g/mL}$ )	13.1	13.8	10.2	13.7	17.4	16.0	14.0	2.5
$AUC_{0 \rightarrow \text{inf}}$ ( $\mu\text{g} \cdot \text{min/mL}$ )	1400	1470	1450	2060	1510	1860	1625	270
$MRT_{0 \rightarrow \text{inf}}$ (min)	192	179	278	345	184	204	230	67

Table 3: Pharmacokinetic values obtained from serum concentrations of ceftiofur and metabolites after intravenous administration of a single dose of ceftiofur sodium at a dose of 2.2 mg ceftiofur free acid equivalents/kg (1.0 mg/lb) in non-lactating dairy goats.

Parameter	Animal Number						Mean	Std. Dev.
	2025	9047	9039	9048	2058	0003		
T <sub>1/2a</sub> (min)	68.9	31.2	46.4	66.6	56.3	41.1	48.0	(harmonic)
T <sub>1/2β</sub> (min)	290	196	227	417	304	200	254	(harmonic)
Cp <sub>0</sub> (μg/mL)	14.0	14.5	16.4	16.4	18.2	17.3	16.1	1.6
AUC <sub>0→inf</sub> (μg•min/mL)	1890	1520	2220	2620	2170	1790	2036	383
MRT <sub>0→inf</sub> (min)	209	206	232	336	220	182	231	54

Table 4: Pharmacokinetic values obtained from serum concentrations of ceftiofur and metabolites after intramuscular administration of a single dose of ceftiofur sodium at a dose of 1.1 mg ceftiofur free acid equivalents/kg (0.5 mg/lb) in lactating dairy goats.

Parameter	Animal Number						Mean	Std. Dev.
	1061	9079	9063	2032	8026	9055		
T <sub>1/2a</sub> (min)	20.1	38.7	7.16	42.7	44.0	4.20	12	(harmonic)
T <sub>1/2β</sub> (min)	133	195	124	196	288	133	163	(harmonic)
Cp <sub>max</sub> (μg/mL)	1.56	1.74	3.04	4.67	1.66	3.30	2.66	1.24
t <sub>max</sub> (min)	64.0	127	36.4	28.2	135	29.0	69.9	49.1
AUC <sub>0→inf</sub> (μg•min/mL)	420	730	647	698	966	708	695	175
MRT <sub>0→inf</sub> (min)	220	338	189	197	474	198	269	115
Lag Time (min)		14.2	5.14	5.31		7.44	8.02	4.25

Table 5: Pharmacokinetic values obtained from serum concentrations of ceftiofur and metabolites after intramuscular administration of a single dose of ceftiofur sodium at a dose of 2.2 mg ceftiofur free acid equivalents/kg (1.0 mg/lb) in lactating dairy goats.

Parameter	Animal Number						Mean	Std. Dev.
	2025	9047	9039	9048	2058	0003		
T <sub>1/2a</sub> (min)	14.7	10.5	26.7	23.1	12.9	18.8	16	(harmonic)
T <sub>1/2β</sub> (min)	117	159	2.46	195	91.7	279	156	(harmonic)
C <sub>pmax</sub> (μg/mL)	5.15	4.53	3.25	4.85	5.94	3.76	4.57	0.96
t <sub>max</sub> (min)	56.5	45.9	111	86.9	42.7	78.9	70.4	26.6
AUC <sub>0→inf</sub> (μg•min/mL)	1170	1260	1510	1810	1080	1840	1447	328
MRT <sub>0→inf</sub> (min)	190	2.45	394	314	151	430	287	112
Lag Time (min)	6.09	1.71	15.1	6.35	0.31	0.39	5.0	5.7

(2) Physical examination:

All animals remained healthy throughout the duration of the entire study.

(3) Milk samples:

Refer to section VI. HUMAN FOOD SAFETY: CEFTIOFUR SODIUM IN GOATS: RESIDUE CONCENTRATIONS IN MILK

E. Conclusions:

Part 1: Despite the dose-related difference in half life values, the dose proportionality was observed in AUC and CMAX values following both IM and IV drug administration. Accordingly, users may be advised that a doubling of the dose will result in a doubling of the systemic ceftiofur concentrations.

Part 2: Single dose pharmacokinetic estimates can be used to predict the serum total ceftiofur concentrations obtained upon multiple IM administrations of ceftiofur sodium in goats.

Part 3: Ceftiofur kinetics are significantly affected by lactation. Drug exposure appears to be significantly less in lactating as compared to dry goats. This difference in exposure appears to be attributable to a faster elimination rate in lactating animals. It is not clear whether this faster elimination is associated with loss in milk versus some other mechanism since less than 1% of the total ceftiofur dose was eliminated in goat milk.

## V. ANIMAL SAFETY

A. Type of Study: Target animal safety study

B. Name and Address of Investigator: Arthur L. Craigmill, Ph.D.  
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C. General Design of the Investigation:

1. Purpose of the study: To demonstrate the safety of ceftiofur sodium in healthy goats.
2. Test animals: Fifteen goats (5 lactating does, 5 dry does, and 5 wethers).
3. Dosage form: powder reconstituted for injection (50 mg/ml).
4. Route of administration: Intramuscular injection.
5. Dosages used: All goats were injected intramuscularly with 11 mg/kg/day for 15 days. This constitutes 5 times the label dose at 3 times the recommended duration. Untreated controls were deemed unnecessary since initial values for each animal served as the baseline for comparison.
6. Test duration: 15 days following 2 weeks acclimation.
7. Parameters:
  - daily clinical observations;
  - daily body weight;
  - injection site examination;
  - clinical hematology and serum chemistries.

- D. Results: No adverse reactions were observed in goats treated with ceftiofur sodium. Daily observations of the animals revealed only minor deviations from normal, including nasal discharges, mild coughs, changes in fecal consistency, and minor sores, none of which was treatment related. There were no major changes in body weights of the animals throughout the study.

In one animal there was a large hematoma at the injection site that persisted for only one day. There were no other signs that would indicate local irritation or systemic toxicity.

Hematology and serum chemistry values were measured before and after treatment. The mean white blood cell count was elevated for the pretreatment samples, and significantly reduced after treatment, but still above the normal range.

The mean creatine kinase and SDH-37 and the alkaline phosphatase activities were above the normal range in both pre and post treatment samples, but not significantly different from each other. The anion gap, sodium, chlorides, creatinine, glucose, and BUN/creatinine ratio were significantly different after treatment. None were outside the normal limits before or after treatment and are not significant of any untoward effect of treatment.

- E. Conclusion: Ceftiofur sodium is safe for use in goats at the proposed dose. No drug related adverse effects were observed even when administered at 5 times the label dose for three times the indicated treatment period. There were no signs of local irritation or systemic toxicity seen in any of the animals. This is consistent with other studies conducted in sheep. Those studies included animal necropsy and injection site examination, which were not necessary in this study since no adverse signs were observed.

## VI. HUMAN FOOD SAFETY

### CEFTIOFUR SODIUM IN GOATS: EDIBLE TISSUE RESIDUE CONCENTRATIONS IN TISSUE

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- B. Test animals: Twenty mixed-breed goats (fifteen wethers and 5 nonlactating females), 17.7 to 21.5 kg at the start of the study.
- C. Route of drug administration: Intramuscular.
- D. Time and duration of dosing: Daily injections of 2.2 mg ceftiofur free acid equivalents/kg body weight were administered for 5 consecutive days.
- E. Tissue residue results: At 12 and 24 hours following the last dose, 10 animals were slaughtered and edible tissues collected for residue analysis. The tissues were analyzed for ceftiofur and metabolites using an HPLC procedure which converts ceftiofur and metabolites to desfuroylceftiofur acetamide. See Table 1.

Table 1. Ceftiofur and metabolite residues in edible tissues from goats given intramuscular injections of ceftiofur sodium at 2.2 mg ceftiofur free acid equivalents/kg once daily for five days from samples obtained 12 hours and 24 hours after the last injection

Tissue	12 hr. Mean Observed Concentration	Standard Deviation	24 hr. Mean Observed Concentration	Standard Deviation
Muscle	0.06 ppm	± 0.03	0.04 ppm	± 0.03
Liver	0.16 ppm	± 0.05	0.09 ppm	± 0.04
Kidney	0.38 ppm	± 0.21	0.26 ppm	± 0.15
Injection site	0.37 ppm	± 0.31	0.16 ppm	± 0.08

- F. Conclusions: The human food safety data indicate that goats (non lactating and lactating) treated with ceftiofur sodium at the highest recommended dose will require no withdrawal period for the depletion of ceftiofur sodium residue from edible tissue.

Because a multi-point residue depletion study was not conducted, we have assessed the kidney (target tissue) residues against the codified kidney tolerance of 8 ppm in cattle using both a statistical tolerance limit algorithm and a one-sided upper tolerance limit for a single time point calculation for tissue residues at 12 hours withdrawal. From the tolerance limit algorithm analysis, an upper limit of 1.98 ppm is calculated for the regression analysis at 12 hours withdrawal. On the basis of the single point calculation, a one-sided upper tolerance limit of 1.233 ppm is calculated for residues at 12 hours withdrawal. Therefore, the tissue residue data support a zero withdrawal for the use of ceftiofur at doses up to 2.2 mg/kg for five days in goats.

#### CEFTIOFUR SODIUM IN GOATS: RESIDUE CONCENTRATIONS IN MILK

- A. Name and Address of Investigators:

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Department of Environmental  
Toxicology Room 4427 Meyer Hall  
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- B. Test animals: Twelve lactating dairy goats of various breeds, 46 to 71 kg body weight, ranging in age from 2 to 6 years. These were divided into 4 treatment groups.
- C. Route of drug administration: Intramuscular and intravenous.
- D. Time and duration of dosing: Goats were administered ceftiofur sodium at 1.1 mg ceftiofur free acid equivalents (CFAE)/kg body weight (Groups 1 and 3) or 2.2 mg CFAE/kg body weight (Groups 2 and 4). Each animal received both an intravenous dose and an intramuscular dose using a complete two route, two-period crossover design, with a two-week washout between injections. Groups 1 and 3, and groups 2 and 4 were combined, and two weeks after the last injection in the crossover study, were administered ceftiofur sodium intramuscularly for five consecutive days at either 1.1 (groups 1 and 3) or 2.2 mg (Groups 2 and 4) CFAE/kg.

E. Samples: Milk samples were collected twice daily from each goat three days prior to multiple IM dosing, through the treatment period, and for 7 days after the last dose.

F. Milk residue results: See Table 2.

Analysis of milk samples show that residues of ceftiofur in milk during and after treatment are always below 70 ppb, and usually below the limit of detection.

G. Conclusions: The human food safety data indicate that lactating goats treated with ceftiofur sodium at the highest recommended dose will require no withdrawal period for the depletion of ceftiofur sodium residue from milk.

The milk residue data support a zero milk discard for the use of ceftiofur at doses up to 2.2 mg/kg for five days in lactating dairy goats.

The official regulatory analytical method for residues of desfuroylceftiofur in tissues is the HPLC-DCA-BF method. The official analytical method for residues of desfuroylceftiofur in milk is the HPLC-DCA-RE assay.

Table 2. Milk residues of ceftiofur and metabolites. Residue amounts are in ng/mL

Animal	1	2	3	4	5	6	7	8	9	10	11	12
Dose	1.1 mg/kg BW						2.2 mg/kg BW					
3 days pre tx	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 4 AM (pre tx)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 4 PM	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ	<LOQ*	<LOQ	<LOQ*
Day 5 AM (pre tx)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 5 PM	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ*	<LOQ*	<LOQ*	54	<LOQ
Day 6 AM (pre tx)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 6 PM	68	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ*	<LOQ*	<LOQ*	<LOQ*	<LOQ*
Day 7 AM (pre tx)	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 7 PM	45	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ	<LOQ*	<LOQ*	<LOQ*	<LOQ*	<LOQ
Day 8 AM (pre tx)	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Day 8 PM	33	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ*	<LOQ*	<LOQ*	31	<LOQ*	<LOQ*
Day 9 AM	<LOQ*	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ*	<LOQ	<LOQ
Day 9 PM	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Days 10 thru 15	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ

\*The limit of detection (LOD) for the method is 15 ppb and the limit of quantification (LOQ) is 31 ppb.

**VII. LABELING**

Goats: Administer to goats at the dosage of 0.5 to 1.0 mg ceftiofur per pound of body weight (1-2 mL reconstituted sterile solution per 100 lbs body weight). Treatment should be repeated at 24-hour intervals for a total of three consecutive days. Additional treatments may be given on days four and five for animals which do not show a satisfactory response (not recovered) after the initial three treatments. Selection of dosage (0.5 to 1.0 mg/lb) should be based on the practitioner's judgement of severity of disease (i.e., extent of elevated body temperature, depressed physical appearance, increased respiratory rate, coughing and/or loss of appetite). Pharmacokinetic data indicate that elimination of the drug is more rapid in lactating does. For lactating does, the high end of the dose range is recommended.

### VIII. AGENCY CONCLUSIONS

The data submitted in this public master file (PMF) are supporting information for the effectiveness, target animal safety and human food safety data required by Section 512 of the Food, Drug, and Cosmetic Act with regard to the proposed use of injectable ceftiofur sodium sterile powder for the treatment of goat respiratory disease (pneumonia) associated with *Pasteurella (Mannheimia) haemolytica* and/or *Pasteurella multocida*. Goats are a minor species of animals defined in 21 CFR 514.1(d). The data submitted meet the requirements of that regulation, and FDA's "Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Minor Use of Animal Drugs" (April 1986). FDA will consider this information along with other required data as support for NADAs that may be filed for this use of ceftiofur sodium sterile powder in goats.

The human food safety data demonstrate that when ceftiofur sodium is administered to goats at doses up to 2.2 mg ceftiofur free acid equivalents/kg body weight, neither a milk discard period nor a preslaughter withdrawal period is required.

FDA is publishing a notice of availability of this PMF to encourage sponsors to file new animal drug applications (NADAs) for ceftiofur sodium sterile powder for the use covered by the PMF. Sponsors will need to submit the remaining data and information required for approval of an NADA.

Ceftiofur sodium sterile powder is currently approved for use in:

Cattle (0.5 to 1.0 mg/lb., IM),  
swine (1.36 to 2.27 mg/lb., IM),  
day-old chickens (0.08 to 0.20 mg per chick, SC),  
day-old turkeys (0.17 to 0.5 mg per poult, SC),  
horses (1.0 to 2.0 mg/lb., IM), dogs (1.0 mg/lb., SC), and  
sheep (0.5 to 1.0 mg/lb., IM).  
See 21 CFR 522.313.

cc:

Courtesy copy for the sponsor  
HFV-199/PMF 5671 A-0000  
HFV-133 (Das)  
HFV-2 (Special Mailing List)  
HFV-12 (FOI Staff)  
HFV-102 (GADQC Reserve Copy)  
HFV-102 Green Book (NTurner)  
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